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(54) WOVEN TUBULAR GRAFT WITH REGIONS OF VARYING FLEXIBILITY

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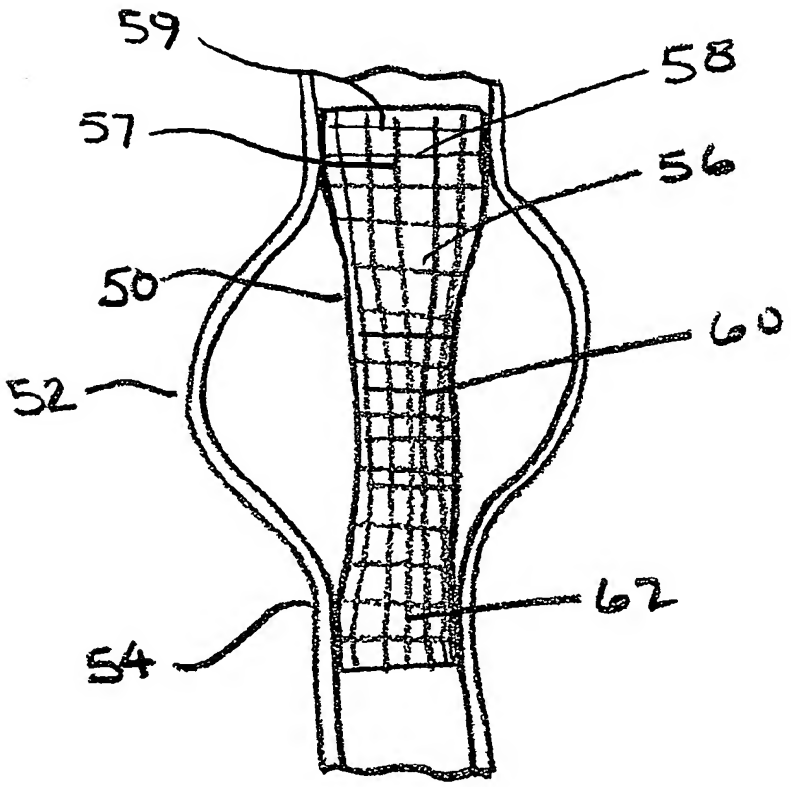
(57) ABSTRACT

A woven tube having a warp direction oriented lengthwise to the tube and a fill direction oriented circumferentially of the tube is disclosed. The tube is woven from a plurality of elastic warp yarns arranged parallel to the warp direction and a plurality of elastic fill yarns arranged parallel to the fill direction. The tube has one or more discrete regions of relatively greater flexibility formed in either the warp or fill directions at locations along the tube. The flexibility is oriented in the warp direction or the fill direction by weaving either the warp or fill yarns, respectively, under relatively less tension.



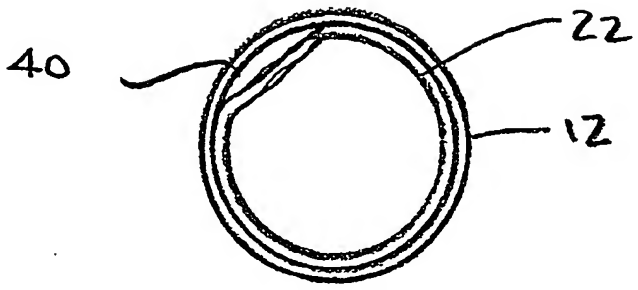


FIG 6
(PRIOR ART)

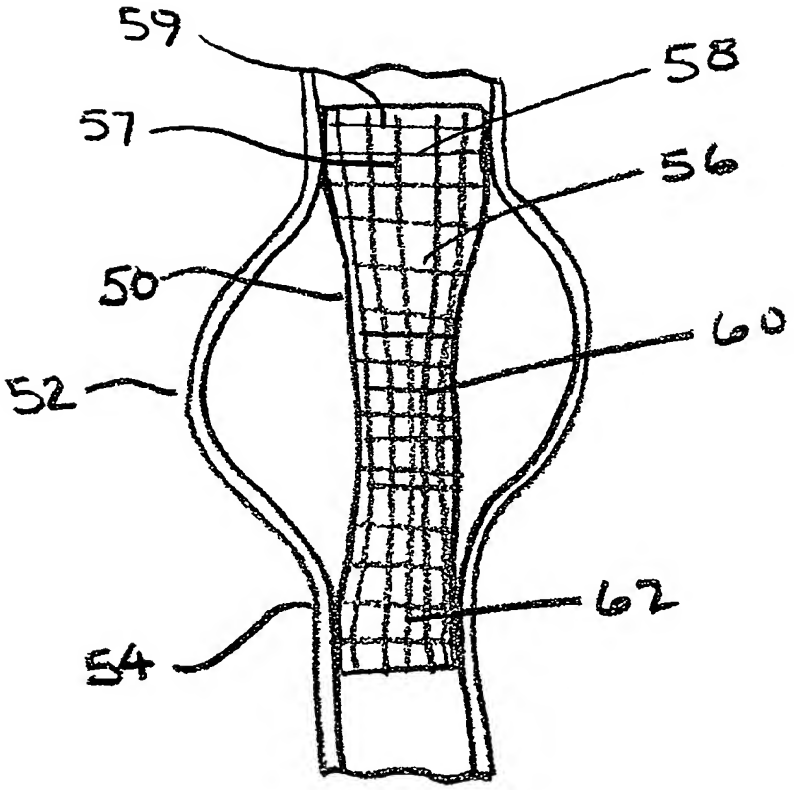


FIG 7

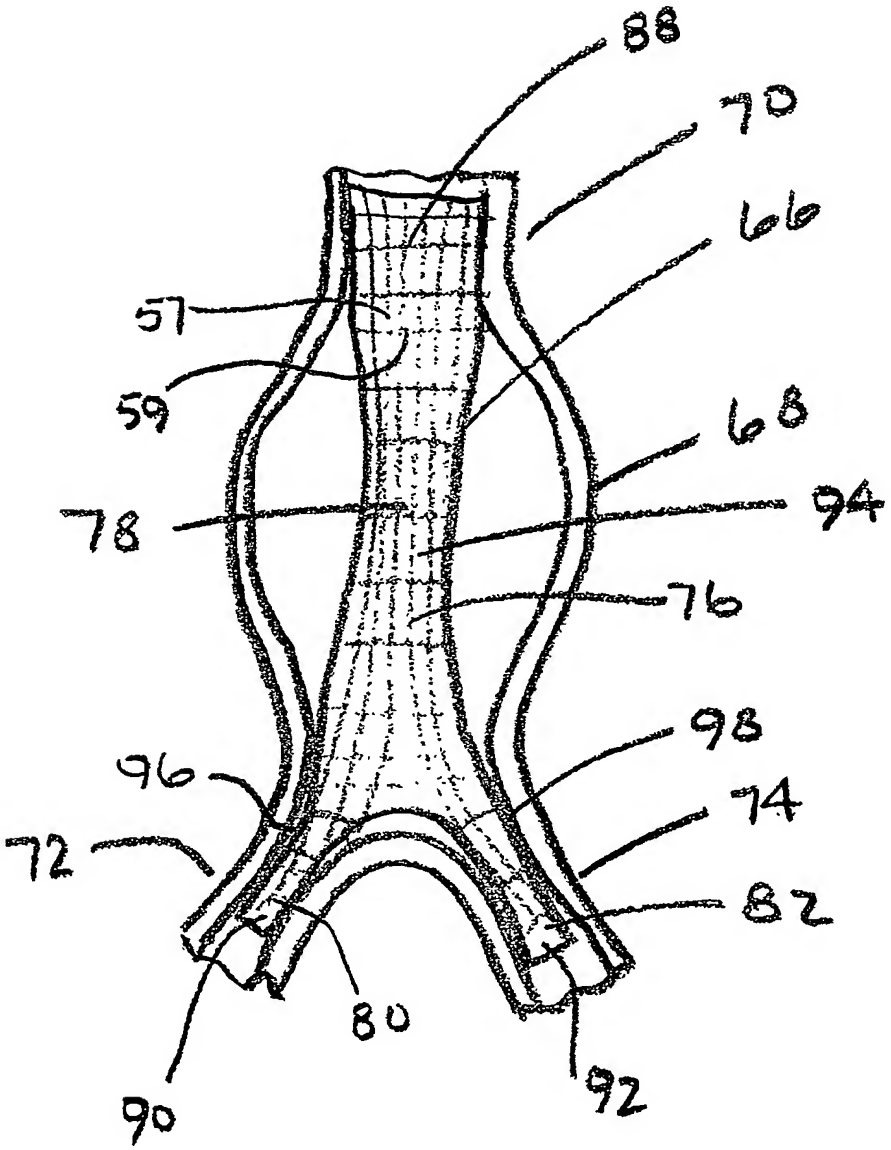
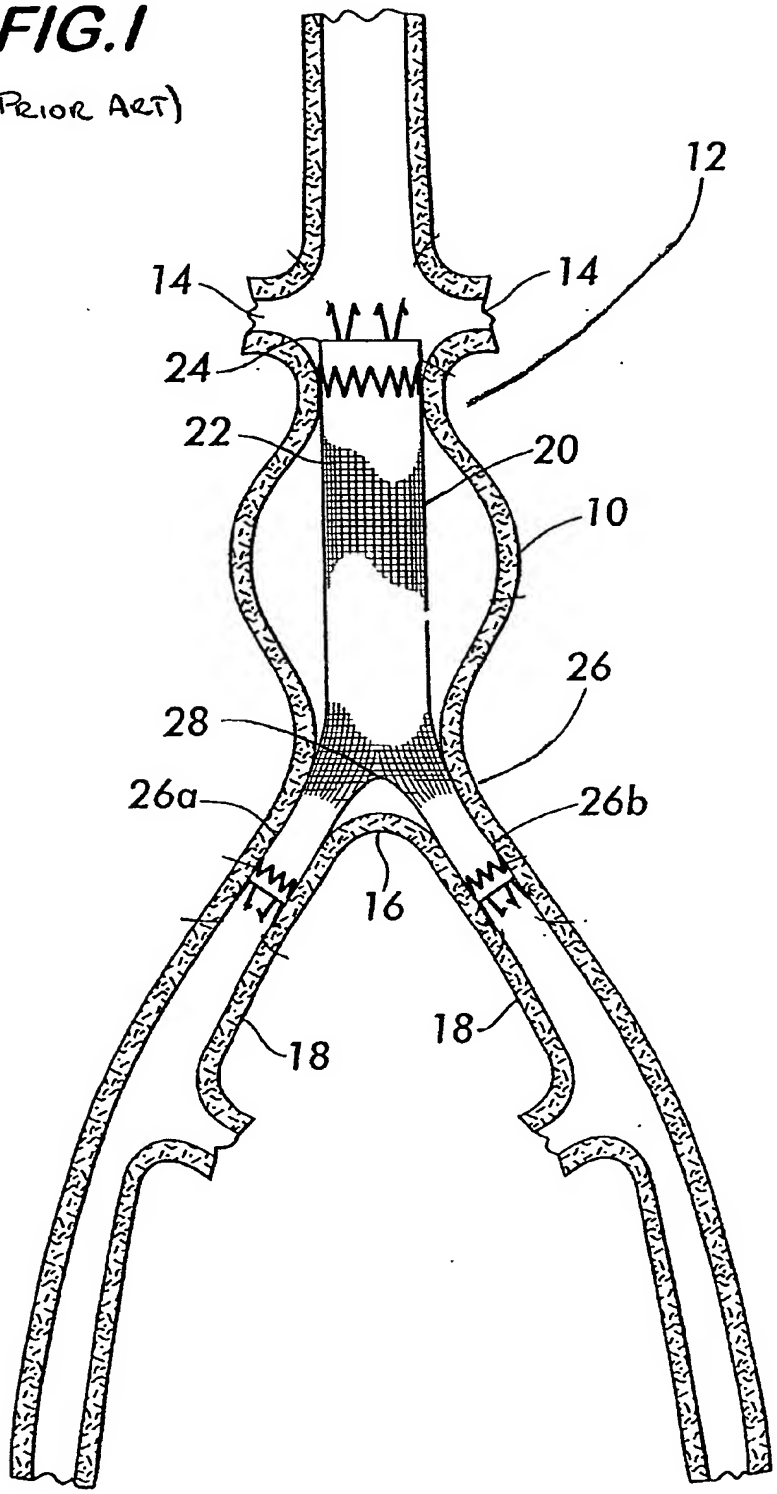


FIG 8

FIG.1
(PRIOR ART)



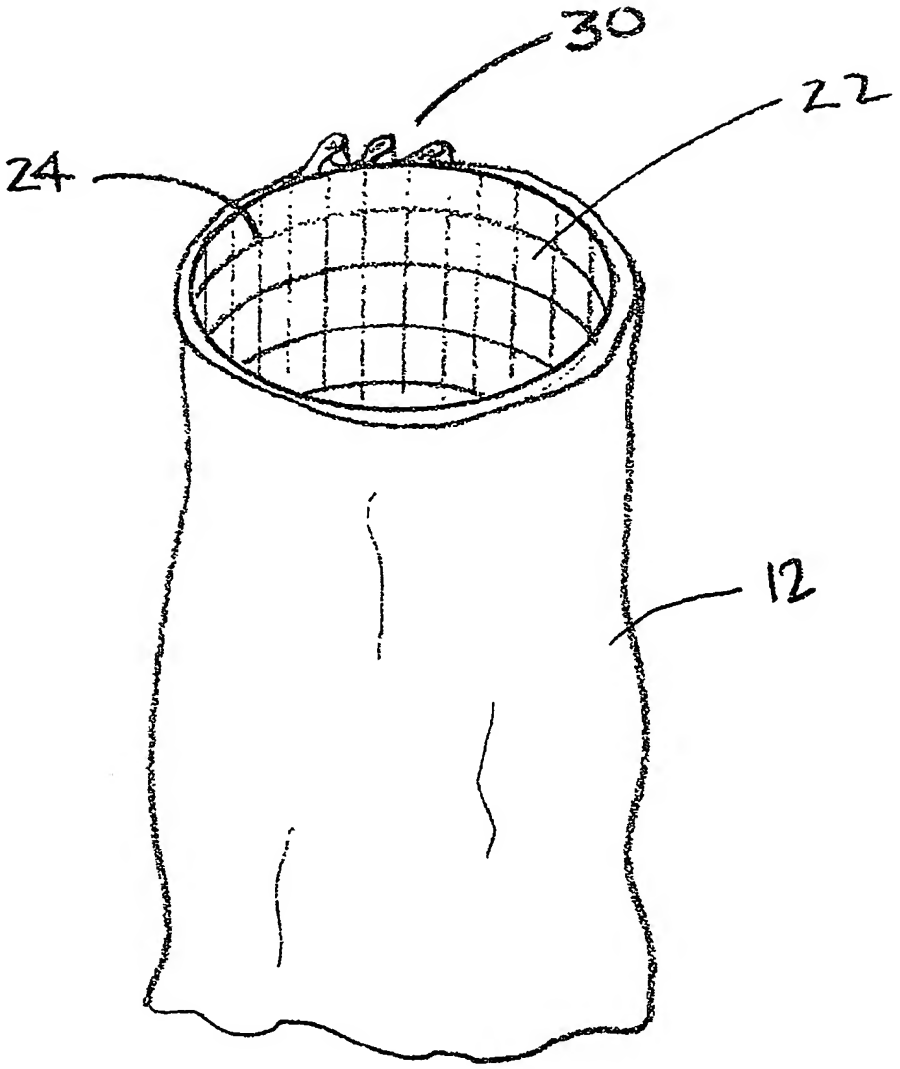


FIG 2
(PRIOR ART)

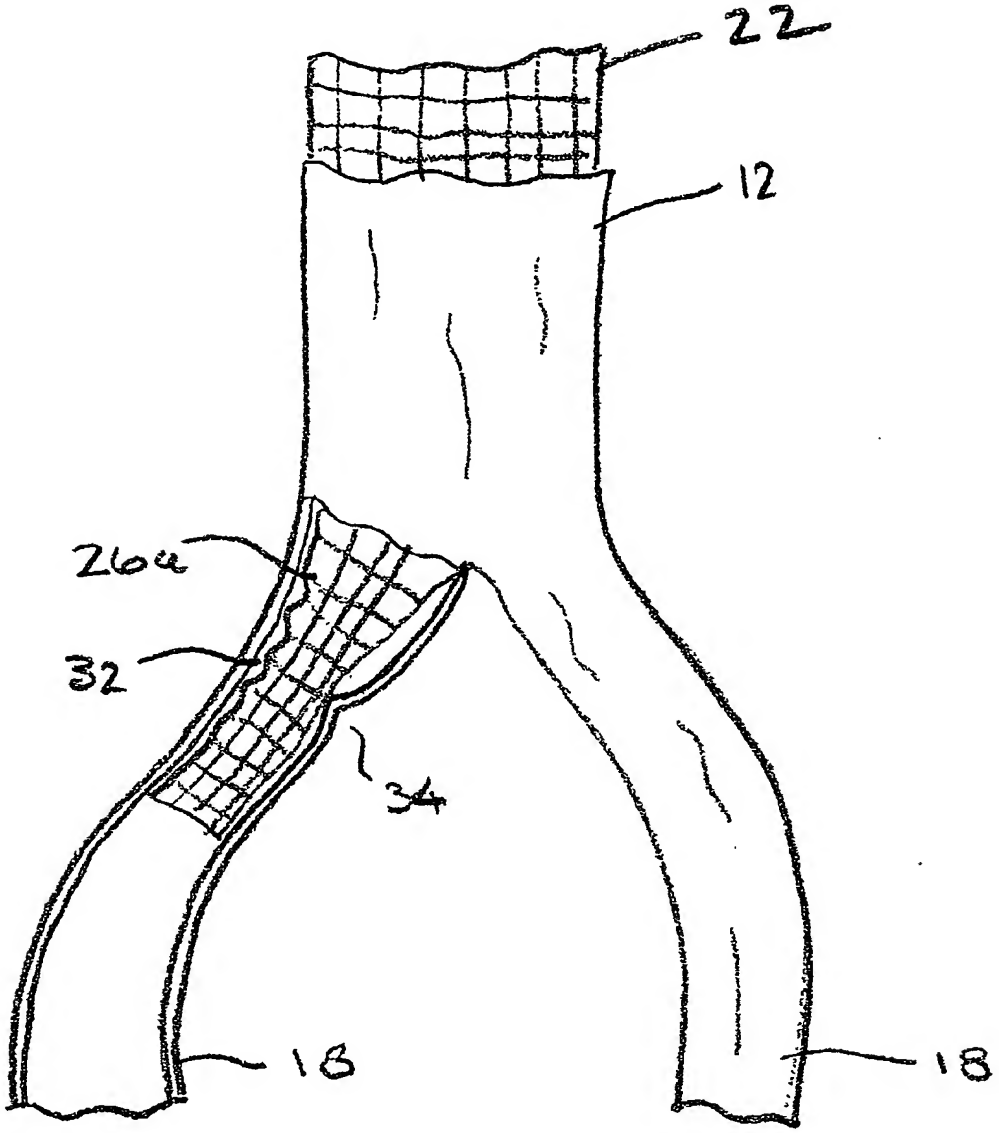


FIG 3
(PRIOR ART)

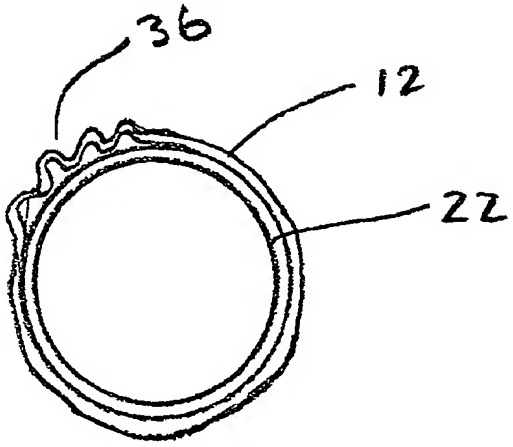


FIG 4
(PRIOR ART)

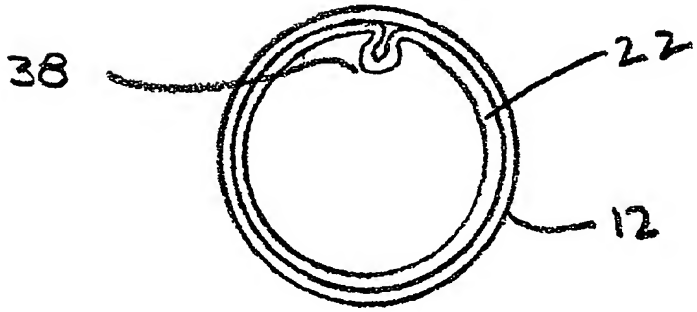


FIG 5
(PRIOR ART)

WOVEN TUBULAR GRAFT WITH REGIONS OF VARYING FLEXIBILITY

RELATED APPLICATION

[0001] This application is based on and claims priority of U.S. Provisional Application No. 60/244,240, filed Oct. 30, 2000.

FIELD OF THE INVENTION

[0002] This invention relates to woven tubular grafts having selected regions of varying flexibility and particularly to woven bifurcated tubes for use as endoluminal grafts in the treatment of vascular aneurysms.

BACKGROUND OF THE INVENTION

[0003] A vascular aneurysm is a pathologic dilation of a segment of a blood vessel which constitutes a weakened portion of the vessel. **FIG. 1** shows an example of a fusiform aneurysm **10**, such as can occur in the abdominal aorta **12**. The entire circumference of the aorta **12** is dilated and weakened. The majority of these aortic aneurysms are located in the distal abdominal aorta between the renal arteries **14** and the bifurcation point **16** where the abdominal aorta splits into the common iliac arteries **18**.

[0004] An aneurysm in any vascular vessel is a cause of concern, and aortic aneurysms in particular constitute a serious condition, as an acute rupture of the aneurysm is fatal unless an emergency operation is performed. However, even when such operations are performed in time, the mortality rate is still greater than 50%.

[0005] Modern methods of treatment for aneurysms focus on preventing rupture by providing a stent graft which is positioned within the artery at the aneurysm. As seen in **FIG. 1** by way of example, a stent graft **20** comprises a bifurcated fabric tube **22**. Bifurcated fabric tubes are formed of a plurality of interlaced yarns wherein a single tube branches into two or more tubes at a bifurcation point. The term "yarn" as used herein is a generic term for a continuous strand or strands of fibers, filaments or material in a form suitable for knitting, weaving, braiding or otherwise intertwining or interlacing to from a fabric. Various forms of yarn include monofilaments, filaments twisted together, filaments laid together without twist, as well as other configurations.

[0006] Tube **22** may be woven, knitted or braided and has one end **24** which is attached to the inner surface of the artery upstream of the aneurysm **10**. The opposite end **26** of the bifurcated tube is split at a septum **28** into two branch tubes **26***a* and **26***b*. The branch tubes are attached to the inside surfaces of the iliac arteries **18** below the aneurysm **10**. The stent graft **20** is substantially impermeable to blood and replaces the abdominal aorta in the region of the aneurysm **10**, relieving the pressure on the weakened arterial wall and avoiding a potentially fatal rupture.

[0007] For endoluminal stent grafts, which are implanted in the artery through the use of a catheter, woven tubes are preferred because the graft should have as little bulk as possible so that it may be readily collapsible to fit within the lumen of the catheter. As noted above, the graft must also be substantially impermeable in the region of the aneurysm so as to isolate and relieve the pressure on it. Woven structures inherently have relatively minimal bulk when compared to knitted or braided structures having the same dimensions and can readily form a substantially impermeable membrane with low porosity. Because bifurcated grafts, with their multiple tubes, tend to be bulkier than grafts comprising a single tube, the woven structure which minimizes the bulk is especially advantageous.

[0008] The advantages of small bulk and low porosity for woven endoluminal grafts are obtained at a significant disadvantage in that the woven tube is generally unable to stretch elastically in either the radial or longitudinal directions. The lack of flexibility is inherent in woven fabrics due to the limited relative motion afforded to the yarns, which are substantially locked in place due to the nature of the weave and the requirement of impermeability. The lack of flexibility results in the disadvantages described below for the example of the woven bifurcated tube used as a graft for the repair of an aortic aneurysm. It is understood that the examples provided below apply to other than bifurcated tubes in the repair of other types of aneurysms as well.

[0009] Blood vessels are seldom round in cross-section; they tend to be oval, egg-shaped or have irregular shapes due to calcified deposits formed on the inner walls. The woven bifurcated tube must sealingly join the vessel at both its ends, but the lack of radial flexibility inhibits the ability of the tube to adapt to the non-round cross section of the vessel. As shown in **FIG. 2**, this may result in folds **30** in either or both the vessel **12** and the tube **22** where they are joined at upstream end. The folds can result in leakage of blood past the graft at its upstream end and into the aneurysm, placing pressure on the aneurysm and possibly causing it to burst.

[0010] Blood vessels are seldom straight; they tend to curve in complex ways. This is readily apparent in bifurcated vessels such as the abdominal aorta **12** which in which branches **26***a* and **26***b* curve away into the iliac arteries **18** supplying blood to the lower extremities. The lack of longitudinal flexibility inhibits the woven graft from readily bending to follow the curvature of the iliac arteries as they branch away from the aorta. As seen in **FIG. 3**, the branch **26***a* of the woven tube **22** may tend to buckle and bunch up on the inside part of the curve, causing folds **32** which can occlude the lumen of the graft, restricting blood flow. The part of the branch **26***a* on the outside of the curve does not stretch to accommodate the longer path of the artery wall and tends to tug on the artery, perhaps causing a kink **34** in its wall.

[0011] Blood vessels tend to vary in diameter from person to person depending on the physical characteristics of the individual. Due to their inherent lack of radial flexibility, woven tubes of one particular diameter cannot readily adapt to the range of artery sizes among different people. As shown in **FIG. 4**, if the tube **22** is too small in diameter, it may cause folds **36** in the artery **12**, reducing the blood flow and causing leaks past the joint. If the tube is too large, it may tend to form an inward fold **38** and leak, as seen in **FIG. 5**. Therefore, many sizes of grafts must be available so that the appropriate size may be matched to a particular artery size so that a good seal can be obtained between graft and artery.

[0012] Blood vessels tend to enlarge in diameter with the age of the patient. The woven tube **22** generally does not have sufficient radial flexibility to accommodate the expansion of the vessel **12** and may result in a separation **40** of a

portion of the graft from the wall of the vessel as seen in FIG. 6. This may allow leakage into the aneurysm, and in extreme cases the upstream portion of the tube may fold into the lumen, inhibiting the flow of blood through the vessel.

[0013] Woven tubes with little radial or axial elasticity tend to be stiff. This stiffness directly affects the force required to move the stent graft through the lumen of a catheter for positioning the graft within the artery at the aneurysm. The catheter is seldom straight as it must follow the bends and twists of the vessel through which it snakes, and the stiffer the graft is, the more force is required to move it through a twisting catheter lumen.

[0014] There is clearly a need for an endoluminal graft which has minimal bulk so that it will fit within the lumen of a catheter, is substantially impermeable and strong enough to withstand repeated hydraulic pressure cycles caused by hundreds of thousands of heart beats and yet possesses the radial and longitudinal flexibility, allowing it to move with minimal force through a curving catheter and to sealingly accommodate arteries of various shapes, sizes and curvatures without folding or kinking in order to form and maintain a fluid-tight seal between the graft and the artery in the treatment of aneurysms.

SUMMARY AND OBJECTS OF THE INVENTION

[0015] The invention concerns a graft compatible with living tissue, the graft comprising an elongated tube woven from a plurality of warp yarns oriented in a warp direction substantially lengthwise along the tube and a plurality of fill yarns oriented in a fill direction substantially circumferentially around the tube. The warp and the fill yarns are elastic, and the tube comprises a region of relatively greater flexibility oriented in one of the warp and the fill directions.

[0016] The region of relatively greater flexibility is formable in the warp direction by weaving the warp yarns comprising the region under relatively less tension than the tension at which the warp yarns comprising the remainder of the tube are woven. The region of relatively greater flexibility is formable in the fill direction by weaving the fill yarns comprising the region under relatively less tension than the tension at which the fill yarns comprising the remainder of the tube are woven.

[0017] It is advantageous to have a region of relatively greater flexibility oriented in the fill direction and located at one end of the tube, the region of relatively greater flexibility being formed by weaving the plurality of the fill yarns comprising the region under relatively less tension than the tension at which the fill yarns comprising the remainder of the tube are woven. Such a tube may also comprise a second region of relatively greater flexibility oriented again in the fill direction and located at an opposite end of the tube, the second region of relatively greater flexibility also being formed by weaving the plurality of the fill yarns comprising the second region under relatively less tension than the tension at which the fill yarns comprising the portion of the tube between the first and second regions are woven.

[0018] It is also possible to have a third region of relatively greater flexibility oriented in the warp direction and located between the first and second regions of relatively greater flexibility. The third region of relatively greater flexibility is formed by weaving the plurality of warp yarns comprising the third region under relatively less tension than the tension at which the warp yarns comprising the first and second regions of relatively greater flexibility are woven.

[0019] The region of relatively greater flexibility may also be formed in the warp direction by including in the region relatively fewer of the warp yarns per unit area than the number of the warp yarns per unit area comprising the remainder of the tube. Similarly, the region of relatively greater flexibility may also be formed in the fill direction by including in the region relatively fewer of the fill yarns per unit area than the number of the fill yarns per unit area comprising the remainder of the tube.

[0020] The invention also includes a method of making a graft comprising an elongated tube compatible with living tissue and having a region of relatively greater flexibility. The method according to the invention comprises the steps of:

[0021] (1) weaving a plurality of elastic warp yarns oriented in a warp direction substantially lengthwise along the tube at a first predetermined tension with a plurality of elastic fill yarns oriented in a fill direction substantially circumferentially around the tube at a second predetermined tension; and

[0022] (2) weaving at least some of the yarns at a third predetermined tension relatively less than the first and the second tensions thereby forming the region of relatively greater flexibility, the flexibility being greater in the warp direction when the plurality of the warp yarns are woven at the third predetermined tension, the flexibility being greater in the fill direction when the fill yarns are woven at the third predetermined tension.

[0023] According to the method, a plurality of fill yarns may be woven at the third tension over a portion of the tube positioned at one end, thereby forming the region of relatively greater flexibility at the one end, the increased flexibility being in the fill direction.

[0024] Furthermore, the plurality of fill yarns may also be woven at the third tension over a second portion of the tube positioned at an opposite end thereof, thereby forming a second of the regions of relatively greater flexibility at the opposite end of the tube, the increased flexibility also being in the fill direction at the opposite end.

[0025] It is also advantageous to weave the plurality of warp yarns at the third tension over a third portion of the tube positioned between the ends, thereby forming a third region of relatively greater flexibility, the increased flexibility being in the warp direction over the portion between the ends.

[0026] It is an object of the invention to provide a woven graft having regions of differing flexibility in the warp and fill directions.

[0027] It is an object of the invention to provide a woven graft having relatively greater radial flexibility at its ends for accommodating an irregularly shaped vessel.

[0028] It is another object of the invention to provide a woven graft having relatively greater radial flexibility at its ends for accommodating a vessel whose diameter changes over time.

[0029] It is still another object of the invention to provide a woven graft having greater flexibility in the warp direction allowing the graft to stretch lengthwise and follow a curved path within a vessel.

[0030] It is yet another object of the invention to provide a woven graft having relatively greater flexibility without increasing the bulk of the graft.

[0031] It is again another object of the invention to provide a woven graft which will pass through a catheter relatively easily.

[0032] These and other objects and advantages of the invention will become apparent upon consideration of the following drawings and detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] **FIG. 1** is a partial sectional view of a graft according to the prior art;

[0034] **FIG. 2** is a partial perspective view of a graft according to the prior art;

[0035] **FIG. 3** is a partial sectional view of a graft according to the prior art;

[0036] **FIG. 4** is a cross-sectional view of a graft according to the prior art;

[0037] **FIG. 5** is a cross-sectional view of a graft according to the prior art;

[0038] **FIG. 6** is a cross-sectional view of a graft according to the prior art;

[0039] **FIG. 7** is a graft comprising a woven tube according to the invention; and

[0040] **FIG. 8** is a graft comprising a bifurcated woven tube according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0041] The disadvantages of the woven tube enumerated above can be avoided while maintaining its advantages of strength, impermeability and minimal bulk by selectively controlling the elastic properties of the tube during the weaving process to provide a tube having relatively greater flexibility over certain regions and relatively less flexibility in other regions.

[0042] **FIG. 7** shows an endoluminal stent graft **50** used to treat a fusiform aneurysm **52** in an artery **54**. Stent graft **50** comprises a tube **56** woven from a plurality of warp yarns **57** and fill yarns **59** and having three regions, **58**, **60** and **62**, of differing flexibility. Regions **58** and **62** form the upstream and downstream ends, respectively, of the tube **56**, where the tube attaches circumferentially around the artery **54** and must form a seal which will prevent leaks into the aneurysm **52**. As noted above, arteries are not usually round, may have calcified occlusions, are different in size from one another and may tend to expand in diameter with age. In order to ensure a proper seal between the tube **56** and the artery **54**, it is advantageous to provide increased radial flexibility to the tube in regions **58** and **62**. This allows these regions to stretch and match the particular size and shape of the artery and accommodate any surface irregularities caused by deposits or occlusions. The increased radial flexibility also enhances the compliance of the tube, ensuring that the seal between tube and artery is maintained over time as the artery increases in diameter.

[0043] Radial flexibility of the regions **58** and **62** is controlled by using elastic fill yarns **59** in the fill direction circumferentially around the tube and varying the tension and density at which these fill yarns are woven. When relatively greater radial flexibility is desired over the regions, the fill yarns are woven under relatively less tension and/or at relatively lower density (picks per length of tube) than other regions of the tube. Because they are woven under less tension, the elastic yarns are locked into the fabric substantially unstretched and are subsequently able to stretch elastically in the fill direction when required to allow radial expansion of the tube to match the diameter and shape of the artery. The lower density of the fill yarns also increases the radial flexibility as there are generally fewer yarns per unit area which must be stretched, allowing the regions **58** and **62** to be expanded by relatively lower loads than if a higher density of yarns were used. A side benefit of the lower weave density at the end regions **58** and **62** is that it may provide interstices of a size which encourage the ingrowth of endothelial cells which line the artery, thereby effecting a natural seal between graft and vessel.

[0044] It is not desirable that the tube **56** have significant radial flexibility in the region **60** adjacent to aneurysm **52**. This region must maintain its diameter under the hydraulic pressure of the blood as it is pumped through the artery so that it relieves the pressure on the aneurysm **52**. Significant radial flexibility in this region would defeat the purpose of the graft as it would allow the tube **56** to expand and place pressure on the artery at the aneurysm.

[0045] The radially stiff region **60** is formed by weaving the elastic fill yarns comprising the tube under relatively higher tension than the fill yarns in regions **58** and **62**. Preferably, the tension is above the elastic limit but below the ultimate tensile strength of the fill yarns in region **60**. The yarns, stretched by the tension force during weaving and locked in the fabric in the stretched state, are not capable of further significant stretching elastically when radial forces are applied to the interior of the tube, as occurs, for example, due to the hydraulic pressure during heartbeats. The density of the fill yarns may also be increased to provide further radial stiffness to the tube in region **60**. With more yarns per unit length, it requires greater force to radially expand the tube, yielding relatively greater stiffness in the fill direction for the region **60**. Greater yarn density also has the added benefit of reducing the porosity and preventing leakage of blood from the stent graft at the aneurysm.

[0046] The tension of the fill yarns **59** is controlled by the loom's shuttle trigger tension, which can be set to a relatively low value when region **58** is being woven, resulting in substantially unstretched fill yarns and a tube having relatively greater radial flexibility and compliance over region **58**. The shuttle trigger tension may be increased as region **60** is being woven to insert substantially stretched yarns in the fill direction, yielding a relatively stiff tube radially over region **60**. As region **62** is woven, the shuttle trigger tension is again reduced, inserting substantially unstretched fill yarns under low tension and producing a region of the tube having relatively greater radial flexibility and compliance.

[0047] The density of the fill yarns may be controlled by a pick wheel as is well understood in the art.

[0048] The elastic yarns used to weave tube **56** are preferably highly textured yarns of polyester. Polytetrafluoroethylene, polypropylene or other biocompatible materials are also feasible. The textured nature of the yarns provides the required elastic properties. Alternatively, the elastic property of the yarns may be obtained by using inherently elastic materials, such as silicone, polyurethane or rubber to form the yarns. Crimped yarns may also be employed to provide fill yarns wherein the tension may be varied to change the radial stiffness of the tube.

[0049] A practical example of a stent graft **50** may comprise a tube 12 inches in length, 1.2 inches in diameter, having fill yarns of textured polyester of 40 denier initially woven at a shuttle trigger tension of 100 grams and a fill density of 60 picks per inch to form region **58**. The shuttle trigger tension is then increased to 140 grams and the fill density of the fill yarns is increased to 168 picks per inch to weave region **60**, being relatively stiffer in the fill direction. Region **62** is then woven at the same parameters as region **58**, although the parameters need not be the same.

[0050] **FIG. 8** shows a stent graft **66** used to treat a fusiform aneurysm **68** in an aortic artery **70** near the iliac arteries **72** and **74**. Stent graft **66** comprises a bifurcated tube **76** having a main tube **78** and two branch tubes **80** and **82**. Both the main and branch tubes are woven from a plurality of warp yarns **57** and fill yarns **59**, the warp yarns being oriented in a warp direction oriented lengthwise along the main and branch tubes, the fill yarns being oriented in a fill direction circumferentially around the tubes. Bifurcated tube **76** provides an example of a stent graft which will benefit from controlling the flexibility of the tube in both the fill and warp directions.

[0051] As described above for the tube **56**, it is advantageous to provide relatively greater flexibility oriented in the fill direction (circumferentially) in regions of tube **76** such as **88**, **90** and **92** which are areas where the tube requires greater radial compliance and flexibility to effect a seal to the artery. As noted above, relatively low radial flexibility is desired for the region **94** adjacent to the aneurysm. The radial flexibility characteristics for the bifurcated tube **76** are controlled in the same way as described above for the conventional tube **56**, i.e., by controlling the tension under which the fill yarns are woven when forming the various regions of the tube.

[0052] However, for regions **96** and **98** on branch tubes **80** and **82**, it is also advantageous to have relatively greater flexibility in the warp direction lengthwise along the branch tubes. Greater flexibility in the warp direction will permit the branch tubes **80** and **82** to follow the curvature of the iliac arteries **72** and **74** without folding on the inside of the curve or kinking on the outside of the curve as seen in **FIG. 3**.

[0053] The relative flexibility of the branch tubes **80** and **82** in the warp direction over regions **96** and **98** is controlled by using elastic warp yarns in the warp direction and weaving the warp yarns under relatively greater or lesser tension. If relatively greater flexibility in the warp direction is desired, the warp yarns are woven under relatively less tension than other regions of the tube **76**. The warp yarns woven under the lower tension are substantially unstretched when they are woven into the fabric and will, therefore, be able to stretch elastically under load, allowing the tube to stretch lengthwise and accommodate the curvature of the artery. Conversely, if relatively less flexibility is desired in the warp direction, the warp yarns are stretched under relatively greater tension (preferably in excess of the elastic limit) as they are woven into the fabric. The stretched yarns are locked into the fabric by the fill yarns and provide relatively little lengthwise flexibility since they are already stretched above their elastic limit and have little or no elasticity left.

[0054] As with the fill yarns, the warp yarns are preferably highly textured yarns comprised of polyester, polytetrafluoroethylene, polypropylene or other biocompatible materials.

[0055] Further control of the longitudinal flexibility may be provided by weaving the tube **76** with the warp yarns closer or farther apart, thereby controlling the warp yarn density (the number of yarns per unit length). Denser weaves are necessarily woven under relatively higher yarn tension which tends to pre-stretch the yarn, leaving little capacity for the yarn to stretch further once woven into the tube. This results in a tube with relatively less flexibility in the warp direction but achieves relatively low fabric porosity due to the relatively higher yarn density. In contrast, less dense weaves are woven under relatively less tension, and the warp yarns are not pre-stretched to the same degree and, when interwoven to form the tube, consequently allow it to stretch with relatively greater longitudinal flexibility. Such tubes have relatively higher porosity, however, and are, therefore, more permeable. Control of the warp yarn density may be effected by varying the separation of the tines of the comb through which the warp yarns pass on the loom.

[0056] A practical example of a bifurcated tube **76** useable as a stent graft may comprise a main tube 5 inches in length, 1.2 inches in diameter and branch tubes 6 inches in length and 0.7 inches in diameter, the tubes being formed of textured polyester yarns of 40 denier. Fill yarns **59** in regions **88**, **90** and **92** near the ends of the tubes are woven at a shuttle trigger tension of 100 grams and a fill density of 60 picks per inch to provide relatively greater flexibility in the fill direction, allowing the tube to expand radially and accommodate and seal to the vessel **70**. By contrast, the fill yarns in region **94**, located adjacent to the aneurysm **68**, are woven at an increased shuttle trigger tension of 140 grams, and the fill density may be increased to 68 picks per inch to provide relatively less flexibility in the fill direction over region **94**.

[0057] Regions **88** and **94** are woven with warp yarns under a relatively high tension of 10 grams to provide relatively lower warp direction flexibility over these regions. However, the warp yarn tension and density is changed when branch tubes **80** and **82** are being woven. To provide relatively greater warp direction flexibility, thereby allowing the branch tubes to better follow the curve of the iliac arteries **72** and **74**, the warp yarn tension is reduced to 7 grams and the warp yarn density is reduced from 140 to 130 ends per inch.

[0058] Fabric tubes with regions of varying flexibility in the warp and fill directions according to the invention will provide improved stent grafts for the repair of vascular aneurysms. Relatively greater flexibility in the fill direction will provide for a better seal between the graft and the artery, lessening the likelihood of leakage or obstruction of the

artery and allow one size of graft to accommodate a wide range of different size and shape arteries. Relatively greater flexibility in the warp direction will allow the graft to conform to the curvature of the artery as it twists and bends without folding or causing kinking of the vessel. The overall increased flexibility is attained without significantly increasing the bulk of the graft thus allowing the graft to be more easily moved through a catheter for delivery to the site of the aneurysm.

What is claimed is:

1. A graft compatible with living tissue, said graft comprising an elongated tube woven from a plurality of warp yarns oriented in a warp direction substantially lengthwise along said tube and a plurality of fill yarns oriented in a fill direction substantially circumferentially around said tube, said warp and said fill yarns being elastic, at least some of said yarns being woven under relatively less tension than other of said yarns thereby forming a region of said tube having relatively greater flexibility than the remainder of said tube.

2. A graft according to claim 1, wherein said yarns woven under relatively less tension comprise warp yarns, said region of relatively greater flexibility being oriented in said warp direction thereby allowing said tube to stretch lengthwise.

3. A graft according to claim 2, wherein said region of relatively greater flexibility is positioned over a portion of said tube between ends of said tube.

4. A graft according to claim 1, wherein said yarns woven under relatively less tension comprise fill yarns, said region of relatively greater flexibility being oriented in said fill direction thereby allowing said tube to stretch radially outwardly.

5. A graft according to claim 4, wherein said region of relatively greater flexibility is positioned over a portion of said tube at one end thereof.

6. A graft compatible with living tissue, said graft comprising an elongated tube woven from a plurality of warp yarns oriented in a warp direction substantially lengthwise along said tube and a plurality of fill yarns oriented in a fill direction substantially circumferentially around said tube, said warp and said fill yarns being elastic, said tube comprising a region of relatively greater flexibility oriented in one of said warp and said fill directions, said region of relatively greater flexibility being formable oriented in said warp direction by weaving said warp yarns comprising said region under relatively less tension than the tension at which said warp yarns comprising the remainder of said tube are woven, said region of relatively greater flexibility being formable oriented in said fill direction by weaving said fill yarns comprising said region under relatively less tension than the tension at which said fill yarns comprising the remainder of said tube are woven.

7. A graft according to claim 6, wherein said region of relatively greater flexibility is further formable in said warp direction by including in said region relatively fewer of said warp yarns per unit length than the number of said warp yarns per unit length comprising the remainder of said tube, said region of relatively greater flexibility being further formable in said fill direction by including in said region relatively fewer of said fill yarns per unit length than the number of said fill yarns per unit length comprising the remainder of said tube.

8. A graft according to claim 6, wherein said region of relatively greater flexibility is oriented in said fill direction and located at one end of said tube, said region of relatively greater flexibility being formed by weaving said plurality of said fill yarns comprising said region under relatively less tension than the tension at which said fill yarns comprising the remainder of said tube are woven.

9. A graft according to claim 8, further comprising a second region of relatively greater flexibility oriented in said fill direction and located at an opposite end of said tube, said second region of relatively greater flexibility being formed by weaving said plurality of said fill yarns comprising said second region under relatively less tension than the tension at which said fill yarns comprising a portion of said tube between said first named and said second regions are woven.

10. A graft according to claim 9, further comprising a third region of relatively greater flexibility oriented in said warp direction and located between said first named and said second regions of relatively greater flexibility, said third region of relatively greater flexibility being formed by weaving said plurality of said warp yarns comprising said third region under relatively less tension than the tension at which said warp yarns comprising said first named and said second regions of relatively greater flexibility are woven.

11. A graft according to claim 10, wherein said tube comprises a bifurcated tube.

12. A graft according to claim 6, wherein at least one of said plurality of said warp yarns and said fill yarns comprises yarns selected from among the group consisting of highly textured polyester, polypropylene and polytetrafluoroethylene yarns.

13. A graft according to claim 6, wherein at least one of said plurality of said warp yarns and said fill yarns comprises yarns selected from among the group consisting of silicone, polyurethane and rubber yarns.

14. A graft compatible with living tissue, said graft comprising an elongated bifurcated tube comprising a main tube connected with two branch tubes in fluid communication with said main tube, said bifurcated tube terminating in a first end positioned distally from said branch tubes, each of said branch tubes terminating in an end distally from said main tube, said bifurcated tube being woven from a plurality of warp yarns oriented in a warp direction substantially lengthwise along said main and said branch tubes and a plurality of fill yarns oriented in a fill direction substantially circumferentially around said main and said branch tubes, said warp and said fill yarns being elastic, said ends having relatively greater flexibility in said fill direction than said main and said branch tubes between said ends, said ends being formed by weaving said plurality of said fill yarns comprising said ends under relatively less tension than the tension at which said plurality of said fill yarns comprising said main and said branch tubes between said ends are woven.

15. A graft according to claim 14, wherein said main and said branch tubes between said ends have relatively greater flexibility in said warp direction than said ends, said main and said branch tubes between said ends being formed by weaving said plurality of said warp yarns comprising said main and said branch tubes under relatively less tension than the tension at which said plurality of said warp yarns comprising said ends are woven.

16. A graft compatible with living tissue, said graft comprising an elongated tube woven from a plurality of

warp yarns oriented in a warp direction substantially lengthwise along said tube and a plurality of fill yarns oriented in a fill direction substantially circumferentially around said tube, said warp and said fill yarns being elastic, said tube comprising a region of relatively greater flexibility in one of said warp and said fill directions, said region of relatively greater flexibility being formable in said warp direction by including in said region relatively fewer of said warp yarns per unit length than the number of said warp yarns per unit length comprising the remainder of said tube, said region of relatively greater flexibility being formable in said fill direction by including in said region relatively fewer of said fill yarns per unit length than the number of said fill yarns per unit length comprising the remainder of said tube.

17. A graft according to claim 16, wherein said region of relatively greater flexibility is oriented in said fill direction and located at one end of said tube, said region of relatively greater flexibility being formed by including in said region relatively fewer of said fill yarns per unit length than the number of said fill yarns per unit length comprising the remainder of said tube.

18. A graft according to claim 17, further comprising a second region of relatively greater flexibility oriented in said fill direction and located at an opposite end of said tube, said second region of relatively greater flexibility being formed by including in said second region relatively fewer of said fill yarns per unit length than the number of said fill yarns per unit length comprising a portion of said tube between said first named and said second regions of relatively greater flexibility.

19. A graft according to claim 18, further comprising a third region of relatively greater flexibility oriented in said warp direction and located between said first named and said second regions of relatively greater flexibility, said third region of relatively greater flexibility being formed by including in said third region relatively fewer of said warp yarns per unit length than the number of said warp yarns per unit length comprising said first named and said second regions of relatively greater flexibility.

20. A method of making a graft comprising an elongated tube compatible with living tissue and having a region of relatively greater flexibility, said method comprising the steps of:

weaving a plurality of elastic warp yarns oriented in a warp direction substantially lengthwise along said tube at a first predetermined tension with a plurality of elastic fill yarns oriented in a fill direction substantially circumferentially around said tube at a second predetermined tension; and

weaving at least some of said yarns at a third predetermined tension relatively less than said first and said second tensions thereby forming said region of relatively greater flexibility, said flexibility being greater in said warp direction when said plurality of said warp yarns are woven at said third predetermined tension, said flexibility being greater in said fill direction when said fill yarns are woven at said third predetermined tension.

21. A method according to claim 20, wherein said plurality of fill yarns are woven at said third tension over a portion of said tube positioned at one end thereof, thereby forming said region of relatively greater flexibility at said one end, said increased flexibility being in said fill direction.

22. A method according to claim 21, wherein said plurality of fill yarns are woven at said third tension over a second portion of said tube positioned at an opposite end thereof, thereby forming a second of said regions of relatively greater flexibility at said opposite end, said increased flexibility being in said fill direction at said opposite end.

23. A method according to claim 22, wherein said plurality of warp yarns are woven at said third tension over a third portion of said tube positioned between said ends, thereby forming a third said region of relatively greater flexibility, said increased flexibility being in said warp direction over said portion between said ends.

* * * * *

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United States Patent [19]

Schmitt

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[45] Date of Patent: Jan. 24, 1995

[54] THREE-DIMENSIONAL BRAIDED SOFT TISSUE PROSTHESIS

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[73] Assignee: Meadox Medicals, Inc., Oakland, N.J.

[21] Appl. No.: 945,226

[22] Filed: Sep. 14, 1992

[51] Int. Cl.[6] A61F 2/06; A61F 2/04

[52] U.S. Cl. 623/1; 623/12; 600/36

[58] Field of Search 623/1, 11, 12; 600/36; 606/191-198

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[57] ABSTRACT

The present invention provides a soft tissue prosthesis which is formed from a three-dimensional braided structure. The three-dimensional braided structure preferably may be made in the form of a solid three-dimensional braid, a three-dimensional braid having at least one interlocking yarn coupling contiguous layers or in the form of a plurality of two-dimensional braided layers adhesively laminated, separately sewn or otherwise connected together to form the three-dimensional braided prosthesis.

26 Claims, 3 Drawing Sheets

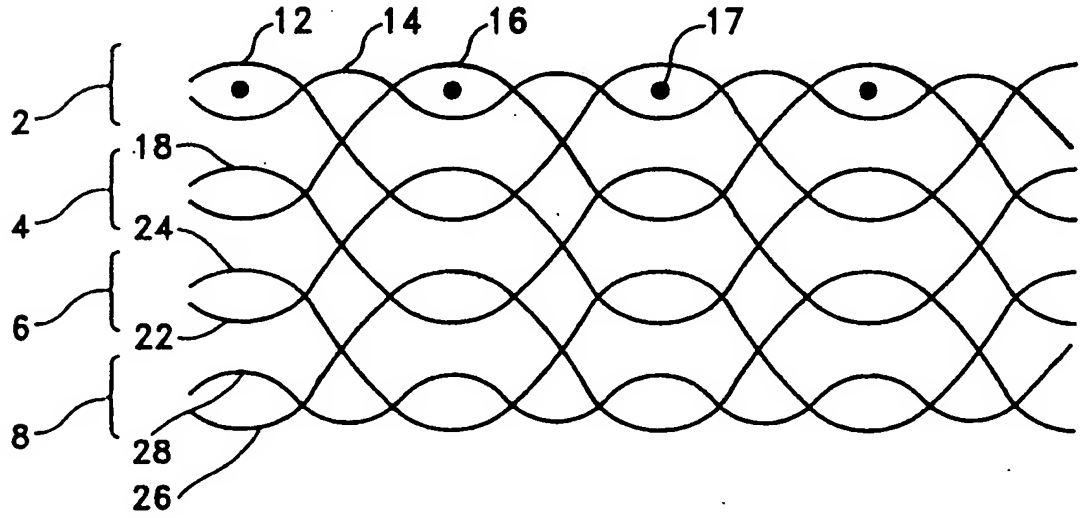


FIG-1

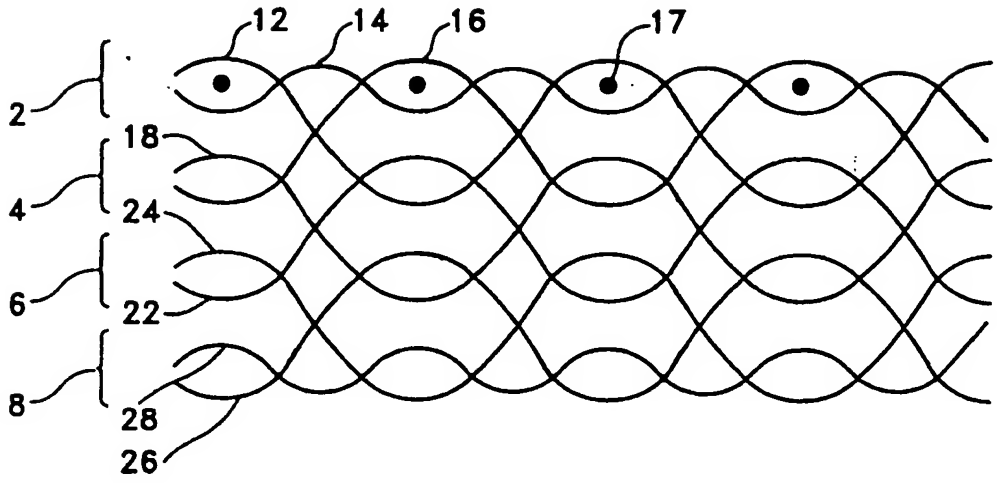


FIG-2

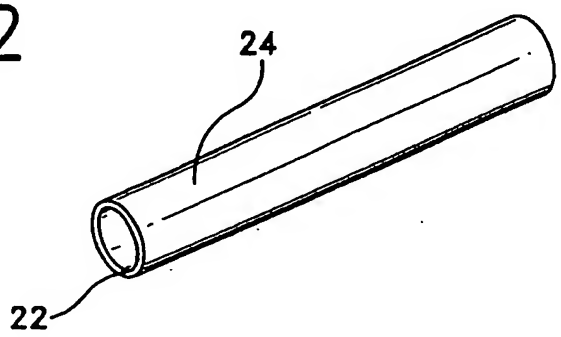


FIG-3

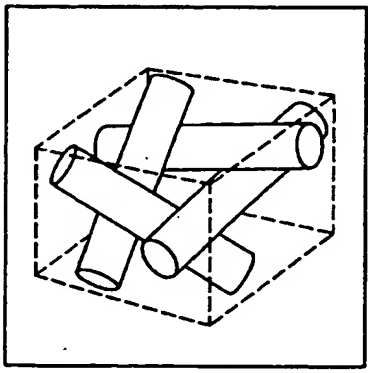


FIG-4

FIG-5

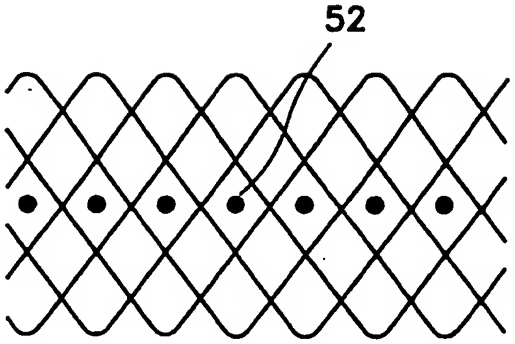


FIG-6

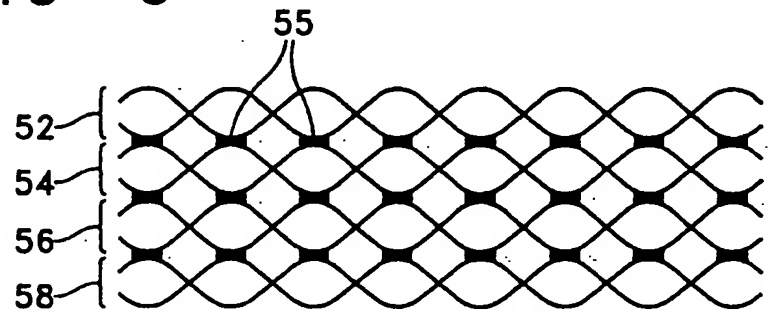


FIG-7

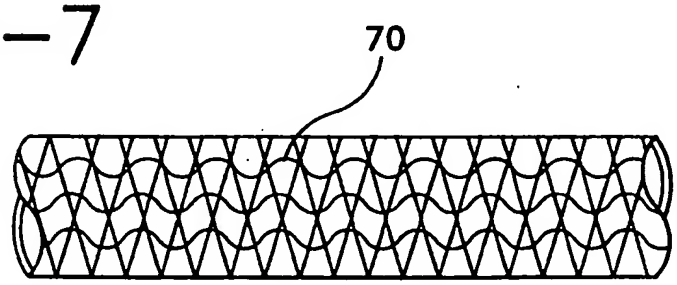
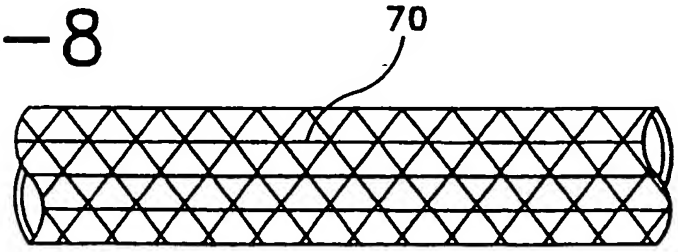


FIG-8



THREE-DIMENSIONAL BRAIDED SOFT TISSUE PROSTHESIS

BACKGROUND OF THE INVENTION

The present invention relates to a braided soft tissue prosthesis and, more particularly, to a soft tissue prosthesis formed from a three-dimensional braided structure.

Vascular grafts are commonly used as soft tissue prostheses to replace damaged or diseased veins and arteries. To maximize the effectiveness of any prostheses it is desirable that it have characteristics which closely resemble that of the natural body lumen.

One particular problem which is encountered is that of thrombosis. Thrombosis, or clotting, occurs when an individual's blood contacts a foreign body. As the blood begins to deposit platelets on the foreign body, a thrombus or blood clot forms. Historically, grafts having a relatively large diameter (greater than 10 mm) have generally proved successful over the long term because the build-up of thrombus that occurs on the interior surface of the graft is not sufficient to substantially obstruct the flow of blood. However, with respect to grafts having a diameter less than 10 mm, the build-up of thrombus on the interior surface of the graft can result in a complete obstruction of the graft in a relatively short period of time.

Presently, conventional tubular prostheses and, more specifically, vascular grafts formed by weaving or knitting synthetic fibers into a tubular structures, are susceptible to kinking or collapsing under varying circumstances, e.g., when the graft is bent during the contraction of surrounding muscle, or when external pressure is applied to the graft. One conventional solution to these problems has focused on the reinforcement of the walls of the vascular graft through the use of helically wrapped reinforcing fibers, reinforcing rings or bands placed externally around the tubular structure. The additional reinforcement of the tubular structure generally has the disadvantage of reducing the radial and/or longitudinal compliance of the graft due to the stiffness of the reinforcing member. A non-compliant graft may reduce the blood flow through the graft, thereby compromising the ability of the prosthesis to perform naturally. Additionally, the reinforcing member generally cannot be penetrated by cellular ingrowth from surrounding tissue and may cause the erosion of the surrounding tissue during contraction.

Another important characteristic associated with soft tissue prostheses is that of porosity. Preferably, the exterior surface of the prosthesis should include pores which are large enough to allow for the entry of connective tissue into the outer periphery of the graft. Conversely, the inner surface of the prosthesis must have pores small enough so that the blood or body fluid passing through the prosthesis will not leak into the prosthesis. Smaller pores on the inner surface of a vascular prosthesis also result in reduced platelet adhesion and a decreased amount of thrombus formation at the inner surface. Typically, a vascular prosthesis having a constant pore size throughout the structure requires pre-clotting in order to avoid leakage through the pores of the prosthesis; however, pre-clotting tends to increase the risk of contamination of the prosthesis as well as create a risk for clots to break off and form emboli.

Conventional tubular maypole (single layer) braided prosthesis have been tried in the past. However, due to their shortcomings, such prostheses have never been commercialized. One of the greatest disadvantages of a conventional tubular maypole braided prosthesis is the scissoring action which occurs under conditions of blood flow. More specifically, as blood is pumped through the graft, the pressure within the graft increases and decreases concurrently with the pumping of the heart, causing the yarns forming the braid to scissor correspondingly with the expansion and contraction of the graft. This scissoring action by yarns of the conventional maypole braided grafts tends to shear tissue which is attempting to grow into the vascular graft, thereby hindering the natural healing process and assimilation of the graft into natural tissue. Contrary to such conventional structures, the present invention concerns structures which due to their three-dimensional character are dynamically more stable and less prone to scissoring.

Yet another disadvantage of presently available woven or conventional tubular maypole braided prostheses is that sutures easily pull out making it difficult to attach the prosthesis to the existing body lumen and to prevent leakage at this junction. Also, since tubular prostheses are typically formed from a synthetic yarn in the form of a tube, the ends of the tube tend to easily ravel. This is true for single layered prostheses in general. Once the ends ravel or fray, suturing to the existing body lumen becomes extremely difficult. These difficulties explain the reason that these single layered braids have not been commercialized.

Accordingly, it would be advantageous to provide a new and improved soft tissue prosthesis that overcomes the previously-described disadvantages associated with presently available prostheses. More specifically, it would be particularly desirable to have a prosthesis which has the following characteristics: controlled porosity; ravel and fray resistance; a radially self-supporting structure to prevent kinking and collapsing of the prosthesis; and longitudinal compliance for ease of implantation and sizing.

SUMMARY OF THE INVENTION

The present invention addresses the problems associated with the prior art and provides a soft tissue prosthesis in the form of a three-dimensional braided structure preferably made from a synthetic material. The three-dimensional braided structure of the present invention is preferably a multi-layered braid, although a solid three-dimensional braided structure may also be formed. In the preferred embodiment, the braid includes a plurality of layers in which at least one strand of each layer extends into an adjacent or contiguous layer to interlock the adjacent layers; however, a graft may be formed in which the layers are interlocked by means other than by part of the braid itself. For example, the layers may be adhesively laminated, separately sewn together or otherwise connected to prevent separation. Preferably, the multi-layered braid of the present invention includes from two to about ten layers. The number of layers will depend on a number of factors such as the particular application involved, denier of yarns used and the strength of the yarn. The interlocking of the layers in the preferred embodiment helps to prevent separation or movement of the layers in relation to each other. Additionally, to enhance resistance to ravelling or fraying, at least one of the layers or yarns included in the three-dimensional braided structure may

be formed from a fusible material, such as a thermoplastic material, which may be subsequently heated to integrally bond or fuse the layer or contiguous yarns into the braided structure.

The braids of the present invention may be used in a wide variety of applications for replacement of or in support of body lumens. For example, vascular grafts are among the most notable applications, but other lumens such as esophagical, intestinal, urethra, bile ducts and the like are contemplated. The term "soft tissue" prosthesis is intended to cover all such applications.

Among the vascular prosthesis areas which are specifically contemplated include, A-V access shunt grafts used for dialysis, small diameter (3–10 mm) peripheral grafts, tapered grafts, aortic arch grafts, dilatible pediatric grafts and vein grafts.

The three-dimensional braid of the present invention is preferably formed from synthetic materials, which are preferably thermoplastics. The thermoplastic may be chosen from a variety of usable thermoplastics which include, but are not limited to polyesters, polypropylenes, polyethylenes, polyurethanes and polytetrafluoroethylenes. The thermoplastic yarns may have a denier from about 20 to about 1000, and preferably from about 40 to about 300, whereby the smaller the denier the finer the yarn. Alternatively, the synthetic material may be in the form of rovings, tapes or other stranded materials. If yarns are used they may be multifilament, monofilament or spun type. Multifilaments are preferred. In applications where enhanced crush resistance is desired, the use of monofilaments may be effective in achieving this end. The yarns can be in the form of any conventional configuration, such as flat (untwisted), twisted, textured or pre-shrunk.

The prostheses of the present invention may be formed from a mixture of different yarns or the layers themselves may be formed from a single type of yarn. This determination will largely be a matter of choice as to the intended application and desired properties of the prosthesis. It is also contemplated that bioabsorbable materials, such as poly (glycolic acid), poly (lactic acid), polydioxanoes, polyoxalates, poly (α-esters), polycarbonates, polyanhydrides, poly acetals, polycaprolactones, poly (orthoesters), polyamino acids, polyurethanes, polyiminocarbonates, polyamindes, poly (alkyl cyanoacrylates), sebacic acid, polyethylene glycol, polyphosphazene, bis (p-carboxyphenoxy) propane, bis (p-carboxyphenoxy) methane and copolymers and mixtures thereof may be used as yarns to form a part of the three-dimensional braid. Yarns made from these materials are intended to be broken down and absorbed into the body, thereby leaving a void or pore behind in the prosthesis. Therefore, in an embodiment using bioabsorbable yarns, the porosity of the prosthesis can be varied and controlled in accordance with a particular absorption rate of the bioabsorbable material.

The type of yarn, the number of layers, the heat-set conditions and the angle at which the braid is formed determines the longitudinal flexibility and radial compliance of the vascular graft of the present invention. It should be noted that in the preferred embodiment, each layer of the multi-layered braid may be formed from a different synthetic yarn to accomplish different structural and functional characteristics required for the intraluminal and extraliminal surfaces of the prosthesis.

Generally, prostheses are designed to balance the longitudinal stretch, the kink resistance and the crush resistance of the structure for the particular application of the prosthesis. The longitudinal stretch of the prosthesis may be from about 5–50% of the unstressed length of the prosthesis, and preferably is about 10–25%. The longitudinal stretch of the prosthesis is directly related to the kink resistance or flexibility of the prosthesis, i.e., the greater the longitudinal stretch, the more kink resistant. Kink resistance can be defined as a ratio of the bending radius to the radius of the prosthesis. Typically, the kink resistance is not more than a 10:1 ratio, and preferably is less than about 5:1. The degree of crush resistance needed in the prosthesis depends upon the application. In some circumstances it is important that the crush resistance be high, while in other applications the crush resistance may be a minimal factor.

In an alternative embodiment, axial yarns may be added to the braided structure to control the amount of longitudinal or axial stretch. The axial yarns may be included in any single layer or in each layer of the braid and may be formed from any number of types of yarn (monofilament, multifilament, fine denier or heavy denier) depending upon the application of the prosthesis being formed. The axial yarns also help to reduce scissoring of the yarns under conditions of pressure increases and reductions within the lumen of the prosthesis by controlling the amount of longitudinal stretch of the prosthesis. The axial yarn reduces the scissoring effect of the yarns by limiting the angle of the braided yarns from dropping below a chosen braid angle measured in relation to the longitudinal axis of the braided structure, for example, 54.5° which is the neutral angle for pressure vessels.

The soft tissue prosthesis of the present invention provides a method for controlling the permeability or porosity at each layer of the prosthesis to correspond to the requisite characteristics. In the preferred embodiment, the prosthesis formed in accordance with the present invention includes relatively small pores at the intraluminal surface and relatively large pores on the outer surface. The intraluminal surface is substantially smooth and preferably has a small porosity to prevent blood leakage as well as to reduce excessive thrombus from forming on the intraluminal surface of the prosthesis. The outer surface preferably has a high porosity to promote ingrowth of connective tissue therethrough. The composite porosity from the intraluminal surface measured using a Wesolowski water permeability test should not exceed 100 ml/minute/cm^2. If a more porous prosthesis is formed, it may be treated, coated, or impregnated with materials such as collagen to make them leak resistant.

Accordingly, a prosthesis may be formed in accordance with the present invention wherein the average pore diameter of the outer surface is larger than the pores formed on the intraluminal surface and the pore size changes progressively within the three-dimensional braided structure. The prostheses of the present invention may include a gradation or differential of properties between their intraluminal and outer surfaces. In a preferred embodiment, the pores of the three-dimensional braided structure form a tortuous path from the intraluminal surface to the outer surface of the prosthesis.

The three-dimensional braided structure of the present invention also has the advantage of being radially self-sustaining. More specifically, the three-dimensional tubular braid is more kink resistant and crush resistant

than conventional woven, knitted or conventional tubular maypole braided (single layer) prostheses of the past, most of which required external support and crimping. The prostheses of the present invention allow for a straight inner wall to be maintained, whereas a crimped prosthesis creates problems in body fluid flow, i.e., undesirable turbulence, and in deposition of material in the peaks and valleys of the crimp. The radially self-sustaining feature of the inventive structures makes them more desirable for use in prostheses having small diameters, and preferably, having a diameter of less than 10 mm and in applications in the body where radial self-sustenance is of concern.

As previously mentioned, the prostheses of the present invention are formed from a three-dimensional braided structure. In this regard, it is possible to form the prosthesis on a shaped article or mandrel. For example, it may be advantageous to form a prosthesis that is tapered in order to more closely match the two ends of the body lumen which it is replacing. Also, in a three-dimensional braiding process, it is possible to form bifurcations, trifurations or multiple tubular structures. These structures may also be formed by joining a plurality of three-dimensional braided tubes by sewing or other appropriate means for attaching the braided structures. Additionally, a three-dimensional braid may be formed on a shaped mandrel or preform to correspond to the curvature of the body lumen being replaced. Preshaping a vascular prosthesis may be advantageous when replacing blood vessels such as the aortic arch, which have exaggerated or sharp bends.

A suitable method of making prostheses in accordance with the present invention includes choosing a mandrel with an outside diameter corresponding to an inside diameter of a natural body lumen which is to be replaced and braiding a three-dimensional braided structure on the mandrel. In the multi-layered prosthesis, the layers can be braided one at a time, i.e., forming a completed layer and braiding over the completed layer to form the next layer, or several layers may be formed simultaneously. The three-dimensional structure is preferably heat-conditioned for a sufficient time and temperature to heat-set the material, preferably thermoplastic yarn, used to form the prosthesis. The braided structure may include a fusible component which when subsequently heated melts to enhance the ravel and fray resistance of the braid. In a preferred embodiment, the three-dimensional multi-layered braid includes a first or inner layer formed from a yarn having a fine denier, a second layer including a stiffening component, a third layer formed from a fusible component, and a fourth or outer layer formed to have a textured surface, i.e. a velour. In this embodiment, the textured outer surface may include relatively large pores to allow ingrowth of connective tissue into the graft and the intraluminal or first layer may include small pores to prevent fluid from leaking out of the prosthesis. The inner layer is also braided to provide a smooth, straight inner surface which enhances fluid flow and resists deposition of materials which may cause stenosis or occlusion.

A preferred form of the three-dimensional braided structure, as well as other embodiments, features and advantages of this invention will be apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a portion of a multi-layered interlocked three-dimensional braided prosthesis formed in accordance with the preferred embodiment of the present invention;

FIG. 2 is a perspective view of a tubular three-dimensional braided structure formed in accordance with the present invention;

FIG. 3 is a schematic illustration of a solid three-dimensional braid unit cell formed in accordance with one embodiment of the present invention;

FIG. 4 is a photograph of an enlarged cross-section of a solid three-dimensional braided structure formed in accordance with one embodiment of the present invention;

FIG. 5 is a cross-sectional view of a portion of a solid three-dimensional braided structure formed in accordance with one embodiment of the present invention;

FIG. 6 is a cross-sectional view of a portion of a vascular graft formed in accordance with an alternative embodiment of the present invention;

FIG. 7 is a side elevational view of a compressed braided structure having axial yarns therein; and

FIG. 8 is a side elevational view of an elongated braided structure having axial yarns therein.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a soft tissue prosthesis and, more specifically, to a three-dimensional braided structure. The prosthesis formed in accordance with the present invention overcomes many of the disadvantages of presently used conventional soft tissue prosthesis including controlling porosity throughout the tubular structure, forming a prosthesis which is longitudinally elastic as well as being ravel and fray resistant and able to hold sutures. As previously described, it is advantageous to design a prosthesis that has characteristics closely resembling the properties of a natural body lumen.

For purposes of this application, the term soft tissue prosthesis is defined as any artificial substitute for a natural body lumen such as a vein, artery, esophagus or a bile duct. Although some of the discussion in the detailed description is directed to use as a vascular graft, it is envisioned that the three-dimensional tubular braided structure of the present invention can be useful as a prosthesis for any soft tissue body lumen. Naturally, the tubular braided structure would be designed to meet the specific requirements of the body lumen it is replacing.

A multi-layered braided structure is defined as a structure formed by braiding wherein the structure has a plurality of distinct and discreet layers. These layers may be bound by interlocking yarns or by adhesive laminates, sewing, or the like.

A solid three-dimensional braided structure is defined as a structure braided with no less than three braiding yarns which are continuously intertwined through the thickness of the braided structure. Solid braids are homogeneous in that all yarns are present throughout the thickness of the braid. These braids can be thought of as a series of plys which are integrally bound through the braid.

An interlocking three-dimensional braid is defined as a braided structure having at least two layers, whereby a yarn is interbraided from a first layer into a contiguous

second layer to interlock the layers of a multi-layered braid.

A three-dimensional braided structure is defined as a braided structure formed in accordance with the definition of a multi-layered braid, a solid three-dimensional braid or an interlocking three-dimensional braid.

In accordance with the present invention, the three-dimensional braid is preferably a multi-layered braid having an interlocking yarn between the layers of the braid as illustrated in FIG. 1. The interlocking yarn extends from one layer into another contiguous layer in order to interlock the layers together.

Referring to FIG. 1, the soft tissue prosthesis of the preferred embodiment of the present invention comprises four layers, 2, 4, 6 and 8, with each layer having at least one interlocking yarn from a contiguous layer. The interlocking yarns are braided into the structure so that the yarn forms part of a first layer, as well as being part of the contiguous layer by forming the interlock. Within each layer, a segment of the braid is formed by an interlocking yarn from a contiguous layer, the layers being interbraided together. The interlocking yarns couple the multiple layers together to form a three-dimensional braid.

In FIG. 1, the first layer 2 forms the outer layer of the interlocking three-dimensional braided structure. The outer layer is formed from a yarn 14 which is exclusively braided into the first layer along with a yarn 12 which is interbraided into the second layer which is contiguous with the first layer and a yarn 16 which is interbraided from the second layer up into the first layer. The second layer 4 is formed from segments of four yarns 12, 16, 18 and 22 which are interbraided.

The next contiguous layer 6 is formed from segments of four yarns 18, 22, 24 and 26 interbraided to form an inner layer in the multi-layered structure. Layer 8 is formed in similar fashion, having three yarns 24, 26 and 28 which are interbraided.

A braiding machine capable of forming the interlocked three-dimensional braid used to form the preferred embodiment of the present invention is described in International Patent Publication No. WO 91/10766, incorporated herein by reference, which describes a braiding machine capable of forming a multi-layered braid having a yarn from one layer interlocking with a contiguous layer. This apparatus will be described later in greater detail.

FIG. 2 is a perspective view of a tubular three-dimensional braided prosthesis formed in accordance with the present invention. The prosthesis is in the form of a tube having an intraluminal surface 22 and an extraluminal or outer surface 24. The three-dimensional braid is formed to provide a balance of properties and give the longitudinal stretch, kink resistance or flexibility and crush resistance required for the particular application. The longitudinal stretch of the prosthesis may be from about 5-50% of the unstressed length of the prosthesis, and preferably is about 10-25%. The longitudinal stretch of the prosthesis has been found to be directly related to the kink resistance or flexibility of the prosthesis, i.e., the greater the longitudinal stretch, the more kink resistant the prosthesis. Kink resistance can be defined as a ratio of the bending radius to the radius of the prosthesis. Typically, the kink resistance is not more than about a 10:1 ratio, and preferably is less than about 5:1. The crush resistance of the prosthesis depends upon the application. In some circumstances it is important that the crush resistance be high, while in other applications the crush resistance may be of minimal concern.

FIG. 3 illustrates a solid three-dimensional braid cell unit formed in accordance with an alternative embodiment of the present invention. The solid three-dimensional braid achieves a seamless, multi-layered tube by continuous intertwining of fibers. The braid cell unit illustrated in FIG. 3 is the smallest unit showing the braid pattern.

FIG. 4 is an enlarged cross-sectional view of a solid three-dimensional braided structure formed by continuous intertwining of the fibers. In a solid three-dimensional braid, every yarn is present in each layer. Typically, three-dimensional braiding machines used to form this type of solid braid include an array of fiber bobbins held in ring or track configurations. Circumferential motion of the array of bobbins to form the braid is accomplished by shifting slotted rings containing the fiber holders. Fibers are directed through the thickness of the braid by shifting the holders between the rings. Reversal of the direction of ring and hold motions during the shift cycle interlocks the fibers as illustrated in the cross-sectional view shown in FIG. 5. Since every fiber undergoes a similar motion, all fibers become entwined in the balanced array as illustrated in FIGS. 4 and 5.

In yet another embodiment of the present invention, a three-dimensional multi-layered braid may be formed from a plurality of individually and separately formed tubular braided layers which are adhesively laminated or sewn together in order to form a soft tissue prosthesis. The tubular layers must be concentric with respect to their mutual longitudinal axis. FIG. 6 illustrates a cross-sectional view of a portion of a prosthesis formed from a plurality of braided layers adhesively laminated together. The graft as shown in FIG. 6 includes four layers 52, 54, 56 and 58 which are coupled together by an adhesive laminate 55 at points of contact between contiguous layers. Each layer may be formed from a type of yarn having characteristics most desirable to its positioning within the prosthesis. For example, when designing a vascular graft, the inner layer which forms the intraluminal surface is preferably braided to have a smooth surface and a low porosity to prevent leakage of blood and excessive thrombus formation. Conversely, the outer surface is preferably braided to have a textured surface to enhance the ingrowth of connective tissue into the vascular graft.

The textured outer layer of this embodiment may also be formed by warp-knitting to create the velour surface. A velour surface is created by a knitting technique described in U.S. Pat. No. 4,193,137, entitled, "Warp-Knitted Double-Velour Prosthesis," the disclosure of which is incorporated herein by reference. An outer layer or tube may be knitted having a thread which passes back and forth through a wall or trellis of the fabric. These loops constitute the velour or pile. The loops on both faces thereof is termed a double-velour fabric. The velour fabric or tube made of the fabric may be placed around a multi-layered braided tubular prosthesis to form the outer layer of the prosthesis. The velour fabric or tube may be adhesively laminated, separately sewn, or otherwise connected to the multi-layered braid of the present invention. Alternatively, a velour-textured yarn may be used in place of another yarn in the braid.

The preferred embodiment of the interlocked three-dimensional multi-layered braid of the present invention includes between two and ten layers. Since the soft

tissue prosthesis of the present invention is a multi-layered structure, a natural feature of such a structure is that it is ravel and fray resistant. Also, a multi-layered braided structure having interlocking yarns will hold a suture better than previously woven or knitted structures used for vascular grafts. The multi-layered braid of the present invention may also include at least one layer including a fusible material. The fusible material may be added to further prevent ravelling or fraying which may occur at the ends of the braid. In such an embodiment, the layer or portion of the layer which is formed from the fusible material, is heated to melt the fusible layer onto the surrounding yarns thereby further enhancing the ravel and fray resistance of the braided Structure and providing a more suitable structure for suturing to a natural body lumen.

A soft tissue prosthesis formed in accordance with the present invention may be formed from braiding elements including yarns, rovings, tapes or other stranded material. Some of the yarns may be bioabsorbable with other yarns being merely biocompatible. By utilizing nonwoven tapes, such as spunbonded fabric slit into, for example, 1/16" widths, a microporous structure can be formed. The spunbonded tapes are also an excellent medium for suturing. In this regard, the spunbonded tape is readily pierced by a suture needle yet possesses high tear strength and positive anchoring. Since these tapes are very thin and narrow, layers of different yarns may be incorporated into the multi-layered braid to provide additional mechanical strength to the prosthesis.

As mentioned above, the three-dimensional braided structure formed in accordance with the present invention may include one or more yarns formed from bioabsorbable materials. Suitable bioabsorbable materials include but are not limited to poly (glycolic acid), poly (lactic acid), polydioxanoes, polyoxalates, poly (α-esters), polycarbonates, polyanhydrides, polyacetals, polycaprolactones, poly (orthoesters), polyamino acids, polyurethanes, polyiminocarbonates, polyamindes, poly (alkyl cyanoacrylates), sebacic acid, polyethylene glycol, polyphosphazene, bis (p-carboxyphenoxy) propane, bis (p-carboxyphenoxy) methane and copolymers and mixtures thereof, provided that these materials can be formed into a fiber suitable for use with the braiding apparatus being used. A bioabsorbable yarn may be used in either a single layer, in several different layers, or as several yarns within a solid three-dimensional structure to form a prosthesis having an initial porosity different from the porosity once the bioabsorbable material has been absorbed into the body. Once absorbed, a void or pore remains in its place. This may be useful in designing a prosthesis having initially small pores to prevent leaking without the use of a sealant or pre-clotting and yet having a greater porosity to enhance ingrowth of connective tissue some time after implantation.

Of particular usefulness in forming the three-dimensional prosthesis are the polyester materials sold under the Dacron brand name. In the preferred embodiment of the present invention, synthetic yarns are used to form the braided prosthesis. The yarns may be flat, twisted, textured or pre-shrunk. Preferably, the yarns are thermoplastic yarns. Thermoplastic yarns suitable for use in forming the vascular graft include, but are not limited to polyesters, polypropylenes, polyethylenes, polyurethanes and polytetrafluoroethylenes. The yarns may be of the multifilament, monofilament or spun type. Multifilaments are preferred, however, where enhanced crush resistance is desired, the use of monofilaments may be effective in achieving this end.

Additionally, the yarn type and yarn denier for each layer are specifically chosen to meet the design requirements (porosity, flexibility and compliance) of the prosthesis, e.g. vascular graft being formed. Yarn denier denotes the linear density of the yarn (number of grams mass divided by 9,000 meters of length). Thus, a yarn having a small denier, e.g. 20, would correspond with a very fine yarn whereas a yarn having a large denier, e.g. 1000, would correspond to a heavy yarn. The yarns used to form the braid of the present invention may have a denier from about 20 to about 1000, and preferably from about 40 to about 300.

The type of yarn chosen and the denier of the yarn are important in order to form a prosthesis and, more Specifically, a vascular graft having proper pore size. Porosity is important when designing a vascular graft because the intraluminal surface must have pores small enough to prevent the graft from leaking blood while the outer surface must have pores large enough to permit ingrowth of connective tissue and promote healing. Since a preferred embodiment of the present invention is a vascular graft having discrete layers, the designer of the graft can create a structure having different properties at each layer of the multi-layered braid. For example, the first or inner layer of the multi-layered vascular graft may be formed from a yarn having a fine denier and braided at a braid angle such that the intraluminal surface will be smooth and have a low porosity. The low porosity will prevent blood from leaking out of the vascular graft and the smooth intraluminal surface reduces excessive formation of thrombus. Conversely, the outermost layer of the vascular graft may be formed from a yarn having a larger denier and having a braid angle such that the surface is textured and has large pores. The high porosity of the outer surface permits connective tissue ingrowth into the vascular graft to promote healing. In the preferred embodiment, the composite porosity from the intraluminal surface to the outer surface measured using a Wesolowski water permeability test should not exceed 100 ml/minute/cm^2. If a more porous prosthesis is formed, it may be treated, coated or impregnated with materials such as collagen to make it leak resistant.

The layers between the outer and inner layers of the vascular graft may be formed so that the pore size changes progressively from layer to layer within the multi-layered braided structure. The pores of the multi-layered braided structure as well as the solid three-dimensional braided structure preferably form a tortuous path from the intraluminal surface to the outer surface of the vascular graft of the present invention. Also, since the intraluminal surface of the graft can be made smooth and braided to have small pores to prevent leakage, the vascular graft of the present invention can be made so that it does not require a sealant, such as collagen, or to be pre-clotted prior to implantation. Thus, the vascular graft of the present invention may be manufactured ready-to-use unlike many woven or knitted conventional vascular grafts.

Another advantage of the three-dimensional braided structure for use as a soft tissue prosthesis or vascular graft is that the structure can be formed to be radially self-supporting. The three-dimensional braided structure can also be formed to provide the desired degree of longitudinal flexibility and stretch by varying the braid

angle at which the braid elements or components are braided. The flexibility and stretch of the graft is also determined by the type of yarn and the denier of the yarn selected to form the braided structure. Thus, the three-dimensional braid of the present invention provides a vascular graft having characteristics which closely resemble that of a natural blood vessel. Also, three-dimensional multi-layered and solid braided vascular grafts having small diameters (i.e., less than 10 mm) may be formed having enhanced crush and kink resistance. Presently, conventional grafts made without external support or without crimping and having diameters less than 10 mm have not proven effective for use as a vascular graft since the graft tends to kink or crush, thereby restricting blood flow through the graft. Additionally, the prosthesis can be formed having a smooth, straight inner wall whereas if crimping is required, the inner wall forms peaks and valleys which creates problems in body fluid flow and deposition of materials in the peaks and valleys of the crimp.

The three-dimensional braided soft tissue prosthesis of the present invention may also be formed on a shaped mandrel in order to form a braid more closely resembling the length of soft body tissue being replaced. More specifically, the three-dimensional braid may be formed on a tapered mandrel or on a bent or curved mandrel to form a prosthesis. For example, if it is desired to replace the aortic arch, a vascular graft having an almost 90° bend will be required. It is possible to form a three-dimensional braided structure on a shaped mandrel which resembles the curvature of the aortic arch. The three-dimensional braid formed on the shaped mandrel provides a self-sustaining structure having an open lumen throughout the bend. Additionally, in a multi-dimensional braided structure, it is possible to form bifurcations, trifurcations or multiple tubular structures. This may be accomplished in a continuous process as the braided prosthesis is being formed, or by joining at least two three-dimensional braided tubes previously formed by sewing or other appropriate means for connecting the braided structures together to form a desired formation. Thus, a three-dimensional braided structure is more versatile in design than conventional woven, tubular maypole braided or knitted vascular grafts.

In an alternative embodiment, axial yarns may be added to the braided structure to control the amount of longitudinal or axial stretch and thereby control the scissoring action of the yarns. The axial yarns also control or limit the longitudinal stretch of the prosthesis so that the surgeon does not hyper-extend the prosthesis beyond its intended range during the implantation procedure. As illustrated in FIG. 1, the axial yarns 17 are longitudinally inserted within the braided structure during the braiding process to form a triaxial structure. A triaxial structure has three yarn axes as opposed to a simple braided structure which is biaxial and has two yarn axes.

Typically, the braided structure is formed having a braid angle from about 54.5° to about 90° with respect to the longitudinal axis of the braided structure, preferably about 54.5° to about 75° and, most preferably, from about 54.5° to about 90°. The yarns of the braid tend to seek equilibrium at a braid angle of about 54.5°, which is the neutral angle for tubular vessels under pressure. Thus, when the braid angle is larger than the neutral angle, when pressure is exerted from within, for example due to fluid flow, the yarns will tend to scissor and to decrease the braid angle thereby elongating or stretching the braided structure in order to reach the neutral angle. Axial yarns 17 are added in some cases to limit the braided structure from stretching beyond a desired amount, and thereby significantly reducing the potential for scissoring action of the yarns. This scissoring or shearing action is detrimental to the healing process. The scissoring action of the strands tends to prevent the tissue and blood vessels from filtrating the pores of the structure.

Axial yarns used to limit the amount of longitudinal stretch in a braided prothesis may be formed from polyester, Teflon, polypropylene yarns or any other suitable material. Upon completion of the braiding process, the braided structure is preferably scoured to remove contaminants and subsequently heat-set. The heat-setting is preferably accomplished by compressing the braided structure onto a mandrel. The mandrel would be of greater diameter than the diameter of the raided structure. As illustrated in FIG. 7, compressing the braid onto the mandrel causes the diameter causes the diameter to increase, decreasing the length of the structure and causing the axial yarns 70 to slacken. Additionally, the angle of the braid becomes greater upon compression of the structure. The heat-setting process is dependent upon the types of yarns used to form the braid.

After heat-setting, the braided structure would be able to stretch longitudinally until the axial yarns 70 become fully extended as illustrated in FIG. 8. The degree of stretch is controlled depending upon the geometry of the braid and the amount of compression during heat-setting.

Additionally, an axial yarn may be dyed and inserted into the braided structure subsequent to or during the braiding process. A dyed axial yarn positioned in the outer surface of the prosthesis aids the surgeon during implantation to indicate whether the prosthesis is straight and not twisted during the procedure. Preferably, the dyed axial yarn is black in color, formed from 70 denier, 54 filament type 55A Dacron™ polyester, produced by Dupont.

A three-dimensional, soft tissue prosthesis formed in accordance with the present invention may be formed by first choosing a mandrel with an outside diameter corresponding to an inside diameter of a natural body lumen which is to be replaced and thereafter braiding a three-dimensional braided structure onto the mandrel. The braided structure is preferably scoured at 80° C. in a water and detergent bath, and thoroughly rinsed, dried, and then rinsed in a hot water bath at about 70° C. to remove trace chemicals and dried. Subsequent to the scouring process, the braided structure is preferably heat-conditioned at a sufficient time and temperature to heat-set the synthetic material forming the prosthesis. Generally, heat-conditioning causes the graft to shrink slightly and densify. The heat-conditioning parameters are chosen based upon the properties of the synthetic yarns being used to form the braided structure. Typically, heat-conditioning is carried out at a temperature range from about 125° C. to about 225° C. using a convection oven for a time of about 20 minutes. Naturally, any known means for heating the structure may be used.

The soft tissue prosthesis and, more specifically a vascular graft formed in accordance with the preferred embodiment of the present invention preferably includes four layers made of thermoplastic yarns. The first layer or layers forming the intraluminal surface is preferably formed from a braiding element having a fine

denier and braided to have a straight, smooth surface and small pores to prevent leakage of blood flowing through the vascular graft. A second layer in the multi-layered structure is preferably formed from a braiding element having stiffening properties. A third layer is preferably formed from a fusible component to further enhance the ravel resistance and fray resistance of the braided structure. A fourth or outer layer is preferably formed from a braiding element which provides the outer layer with a textured surface having relatively large pores to permit ingrowth of surrounding tissue into the vascular graft. Upon completion of the braiding process, the four layer braid formed in accordance with the present invention is preferably heat-conditioned to heat-set the thermoplastic yarns in position and to melt the fusible layer to be integrally formed into the braided structure.

The specifications of the yarns which may be used to form a soft tissue prosthesis in accordance with the embodiments of the present invention are set forth in the following examples. These examples are presented for purposes of illustration only and are not intended to limit the scope of the invention.

EXAMPLE 1

The first example refers to a 6 mm tubular prosthesis formed from an interlocked three-dimensional, multi-layered braided structure. The prosthesis is preferably braided on a mandrel at a braid angle of about 54.5°. The prosthesis includes four interlocked layers made from a variety of yarns. The first or inner (intraluminal) layer is formed from polyethylene terephthalate (PET) polyester yarns, 50 denier, flat, 48 filaments having 48 ends (ends refer to the number of carriers within the braiding machine). The second layer is formed having a fusible component. More specifically, this layer includes a 40 cotton count (spun) Cellbond TM fusible yarn having 12 ends and a 50 denier, flat, PET polyester yarn having 48 ends. Cellbond TM is a biocomponent yarn which has a core and sheath, whereby the sheath has a different melting temperature than the core. The third layer is formed from a 3 mil diameter PET monofilament yarn having 48 ends. This yarn provides the braided prosthesis with a stiffening component. The fourth (outer) layer is formed of PET polyester 50 diener, textured, 48 filament yarn with 48 ends. Upon completion, the braided structure is cleaned or scoured and subsequently heat-conditioned in a convection oven at about 175° C. for about 20 minutes to melt the fusible component and heat-set the PET polyester yarns.

EXAMPLE 2

The second example refers to a 6 mm tubular prosthesis formed from a three-dimensional, multi-layered interlocked braided structure having axial yarns. The structure is preferably braided on a mandrel and includes four layers. The axial yarns may be placed in all the layers or in a single layer. In this example, the axial yarns are placed in the third layer. The first or inner layer is formed from 50 denier, 48 filament, flat PET polyester having 48 ends. The second layer includes a fusible component formed from 40 cotton count Cellbond TM yarn having 12 ends and a 50 denier, flat PET polyester yarn having 36 ends. The third layer includes 24 ends of axial yarns formed from 50 denier, textured PET polyester and a stiffening component made from 3 mil diameter PET monofilament yarn having 48 ends. The fourth or outer layer is formed from a 50 denier, 48 filament, textured PET polyester yarn having 48 ends. Upon completion, the braided structure is cleaned or scoured and subsequently heat-conditioned in a convection oven at a temperature of about 175° C. for about 20 minutes to melt the fusible component and heat-set the PET polyester yarns.

EXAMPLE 3

The third example refers to a 6 mm tubular prosthesis formed from a solid three-dimensional braided structure having six strands forming three plys which are inter-braided through the thickness of the braid. The prosthesis is formed from 50 denier, 48 filament, textured PET polyester yarn on each carrier in the machine, for a total of 144 ends (48 ends per pair or set of yarns). Upon completion of the braid, the structure is cleaned and subsequently heat-conditioned in a convection oven at temperature of about 175° C. for about 20 minutes to heat set the PET polyester yarns.

EXAMPLE 4

The fourth example refers to a 6 mm tubular prosthesis formed from a solid three-dimensional braided structure as described in Example 3, further including axial yarns. The braided structure includes 24 axial yarns of 70 denier, 54 filament, Type 55A Dacron textured PET polyester. The axial yarns are positioned in the center of the solid three-dimensional braid as illustrated in FIG. 5, reference numeral 52. Once again, this structure is preferably cleaned and subsequently heat-conditioned in a convection oven at a temperature of about 175° for about 20 minutes to heat-set the PET polyester yarns.

EXAMPLE 5

The fifth example refers to a 6 mm tubular prosthesis formed from a laminated or fused multi-layered three-dimensional structure. Each layer is formed from a two-dimensional braid which is bonded to its contiguous layer to form the three-dimensional braided structure. Thus, the first layer is braided over a mandrel, the second layer is braided over the first layer, the third layer is braided over the second layer and the fourth layer is braided over the third layer. Each layer is preferably braided having a braid angle of about 54.5°. The first or inner layer is formed from 50 denier, 48 filament, flat PET polyester having 48 ends. The second layer includes a fusible component and is formed from 24 ends of 40 cotton count Cellbond TM along with 24 ends of 50 denier, textured PET polyester. The third layer is braided having a stiffening component and a fusible component. The third layer includes 24 ends of 40 cotton count Cellbond TM along with 24 ends of 3 mil diameter, monofilament PET polyester. The fourth or outer layer is formed from 48 ends of 50 denier, 48 filament, textured PET polyester yarn. Thus, the fusible component is present on the inner layers (second and third layers) to bond the four braided layers together to form the three-dimensional structure. The three-dimensional structure is then cleaned and subsequently heat conditioned in a convection oven at a temperature of about 175° C. for about 20 minutes to melt the fusible component and heat set the PET polyester components.

A suitable apparatus for forming a solid three-dimensional braid in accordance with one embodiment of the present invention is disclosed in U.S. Pat. No. 4,719,837, entitled "Complex Shaped Braided Structures." According to the braiding process disclosed in the above-referenced patent, the braided structure is formed by

moving the braiding yarns in a repeating two-step pattern such that the braiding yarns follow diagonal paths through a multi-layered axial array of yarns that extend longitudinally in the structure. Each of the braiding yarns pass completely through the array before reversing at a point outside of the array. The structure formed by this type of braiding machine is illustrated in FIGS. 3, 4 and 5.

A suitable apparatus for forming a tubular interlocking multi-layered three-dimensional braid in accordance with the preferred embodiment of the present invention is disclosed in the specification as published under International Patent Publication No. WO 91/10766. According to the braiding apparatus and method for forming the braid disclosed in the above-referenced publication, a braided structure is formed having a plurality of interlocked layers. The apparatus for producing such a braided object incudes: a two-dimensional array of rotatable horn gears in toothed engagement; a driving means for driving said array, each horn gear being arranged to rotate in a direction contrary to each interengaging gear; track means overlaying said array; and a plurality of yarn package carriers movable along said track means by said horn gears. The track means includes a plurality of track modules which together define a plurality of serpentine paths extending in a first direction and in which selected track modules include at least one cross-over path section extending in a second direction between one serpentine path and the next adjacent serpentine path to cause or allow the package carriers to move between adjacent serpentine paths to effect interbraiding of yarns between adjacent layers. The braided structure formed by this machine is illustrated in FIG. 1.

In order to form the laminated multi-layered braided structure, any known two-dimensional conventional braiding machine may be used. Each layer of the structure is braided on top of its contiguous layer to form the three-dimensional structure as illustrated in FIG. 6. As previously described, the layers of this structure are bonded together by any known technique.

Although the illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention.

What is claimed is:

1. A prosthetic device, comprising:

an implantable tubular three-dimensional braided structure wherein said braided structure includes a plurality of interconnected layers, and

wherein said structure has an inner fluid contacting surface and an outer tissue contacting surface, and

wherein said inner surface has a porosity sufficient to discourage leakage of fluid therethrough and said outer surface has a porosity sufficient to allow growth of tissue therein.

2. The prosthesis according to claim 1, wherein both said outer and inner surfaces include pores, and wherein the average pore size on said outer surface is greater than the average pore size on said inner surface.

3. The prosthesis according to claim 2, wherein said pores form a tortuous path from said inner surface to said outer surface.

4. The prosthesis according to claim 3, wherein said braided structure has a porosity as determined by water permeability of less than about 100 ml/minute/cm^2.

5. The prosthesis according to claim 3, wherein said braided structure is impregnated with a leak-resistant material.

6. The prosthesis according to claim 5, wherein said leak-resistant material comprises collagen.

7. The device according to claim 1, wherein said braided structure includes from two to ten braided layers; and

wherein said layers are formed from non-homogenous materials whereby said layers have differing physical properties.

8. The device according to claim 1, wherein said braided structure includes from two to ten braided layers; and

wherein at least one of said layers includes a fusible yarn which may be subsequently heated to integrally bond said implantable three-dimensional tubular braided structure whereby ravel and fray resistance is improved.

9. The device according to claim 1, wherein said braided structure includes from two to ten braided layers; and

wherein at least one of said layers includes an axial yarn to control longitudinal extension of said device.

10. The device according to claim 9, wherein said axial yarn is colored to provide a visual indication of twisting during implantation of said device.

11. The device according to claim 1, wherein said braided structure is formed from a synthetic material.

12. The device according to claim 11, wherein said synthetic material comprises a thermoplastic polymer.

13. The device according to claim 1, wherein said braided structure is formed from yarns having a denier of from about 20 to about 1000.

14. The device according to claim 13, wherein said yarns have a denier of from about 40 to about 300.

15. The device according to claim 13, wherein said inner surface is formed from a fine denier yarn and said outer surface is formed from a heavy denier yarn.

16. The device according to claim 15, wherein said inner surface is smooth to reduce excessive formation of thrombus.

17. The device according to claim 1, wherein said braided structure is formed with a braid angle of from about 54.5° to about 75°.

18. The device according to claim 17, wherein said braid angle is about 54.5°.

19. The device according to claim 1, wherein said braided structure is formed with a longitudinal stretch of from about 5 to about 50%.

20. The device according to claim 19, wherein said longitudinal stretch is from about 10 to about 25%.

21. The device according to claim 1, wherein said braided structure includes layers which are adhesively laminated together.

22. The device according to claim 1, wherein said braided structure includes layers which are sewn together.

23. The device according to claim 1, wherein said braided structure is a vascular graft sized and dimensioned to match a damaged blood vessel removed from an individual.

24. The device according to claim 23, wherein said braided structure is tapered.

25. The device according to claim 23, wherein said braided structure is bifurcated.

26. The device according to claim 1, wherein said braided structure includes first, second, third and fourth layers; and

wherein said first layer forms said inner surface and includes a fine denier yarn for providing said inner surface with smooth low-porosity characteristics; and

wherein said second layer includes an element for imparting stiffening properties to said braided structure; and

wherein said third layer includes a fusible component which may be subsequently heated to integrally bond said layers whereby ravel and fray resistance is improved; and

wherein said fourth layer forms said outer surface and includes a heavy denier yarn for providing said outer surface with textured high-porosity characteristics.

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US006689158B1

(12) **United States Patent**
White et al.

(10) **Patent No.: US 6,689,158 B1**
(45) **Date of Patent: *Feb. 10, 2004**

(54) **INTRALUMINAL GRAFT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation of application No. 09/071,731, filed on May 1, 1998, which is a continuation of application No. 08/446,672, filed as application No. PCT/AU94/00586 on Sep. 29, 1994, now Pat. No. 5,782,904.

(30) **Foreign Application Priority Data**

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(52) **U.S. Cl.** **623/1.13**; 623/1.32; 623/1.35; 623/1.36

(58) **Field of Search** 623/1.13, 1.14, 623/1.32, 1.33, 1.35, 1.36, 1.1, 1.12, 1.15, 1.16, 1.18, 1.22, 1.23, 1.34

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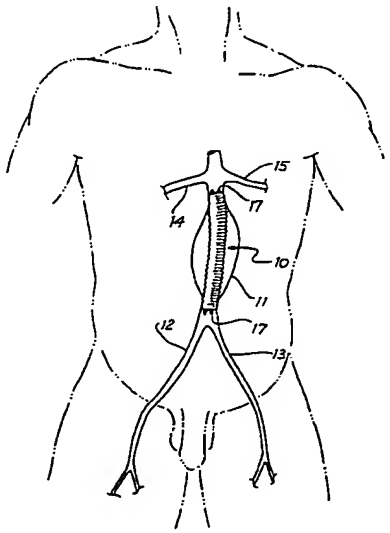
(57) **ABSTRACT**

An intraluminal graft includes a tubular graft body extending along a cylindrical axis, a plurality of wires spaced apart from each other and arranged to circumferentially reinforce said tubular graft body along a substantial portion of its length, and a body surface including an inner surface region and an outer surface region. The body surface defines a plurality of apertures extending from an exterior space, and a first portion of a first wire is in the interior space while a second portion of the first wire is in the exterior space.

23 Claims, 4 Drawing Sheets



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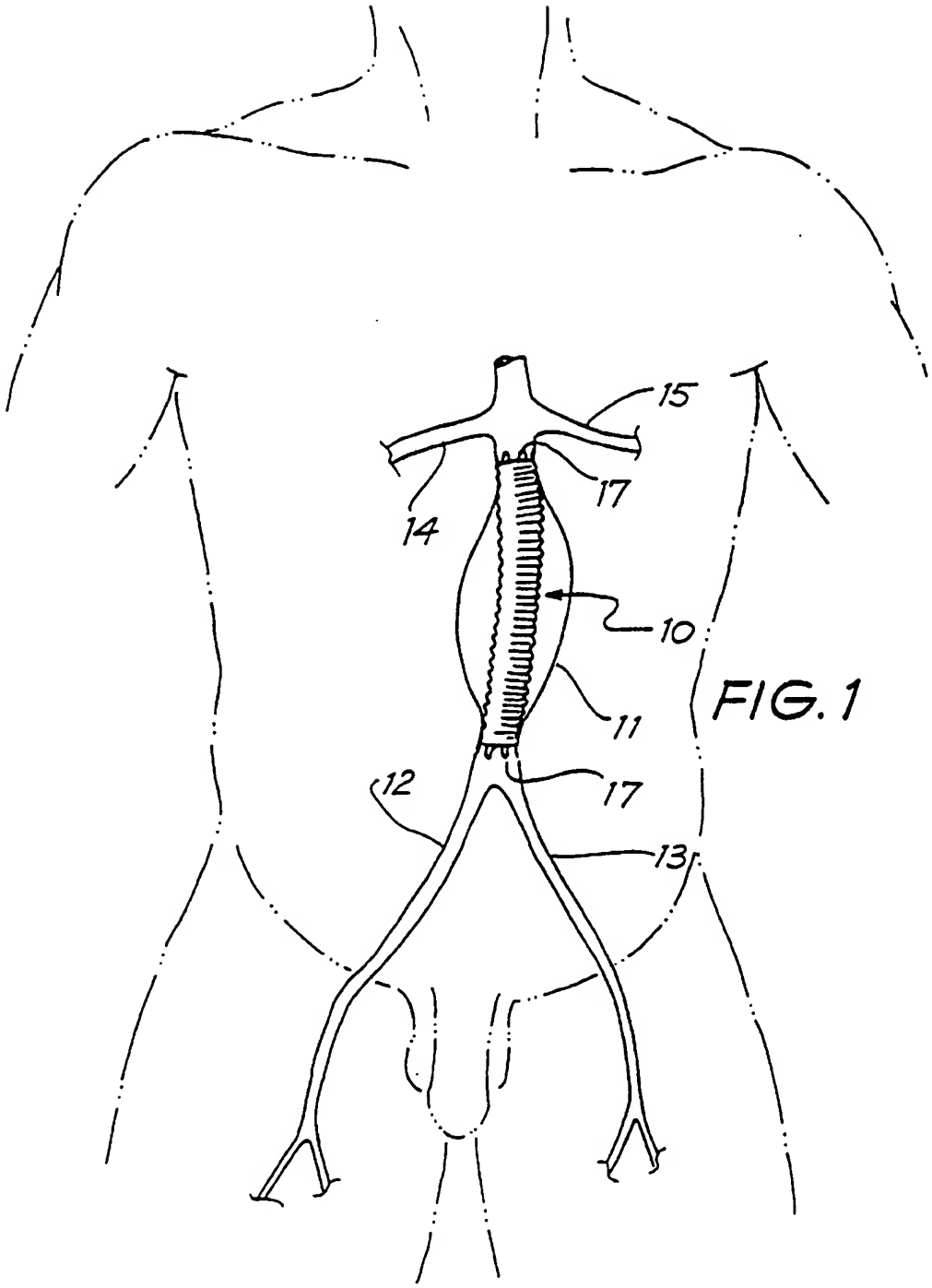


FIG. 1

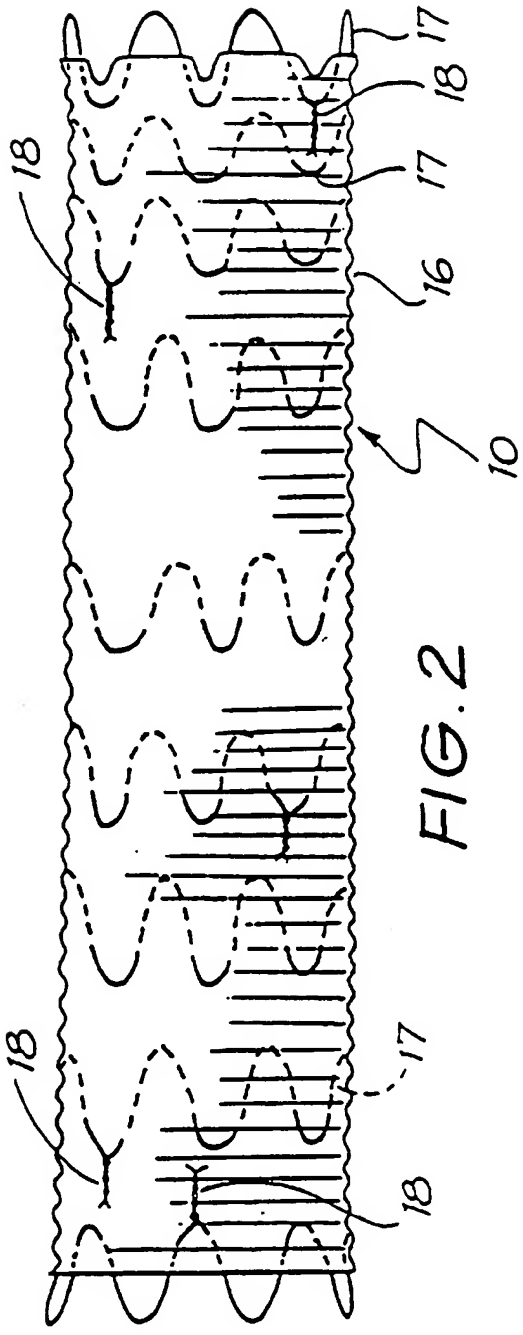


FIG. 2

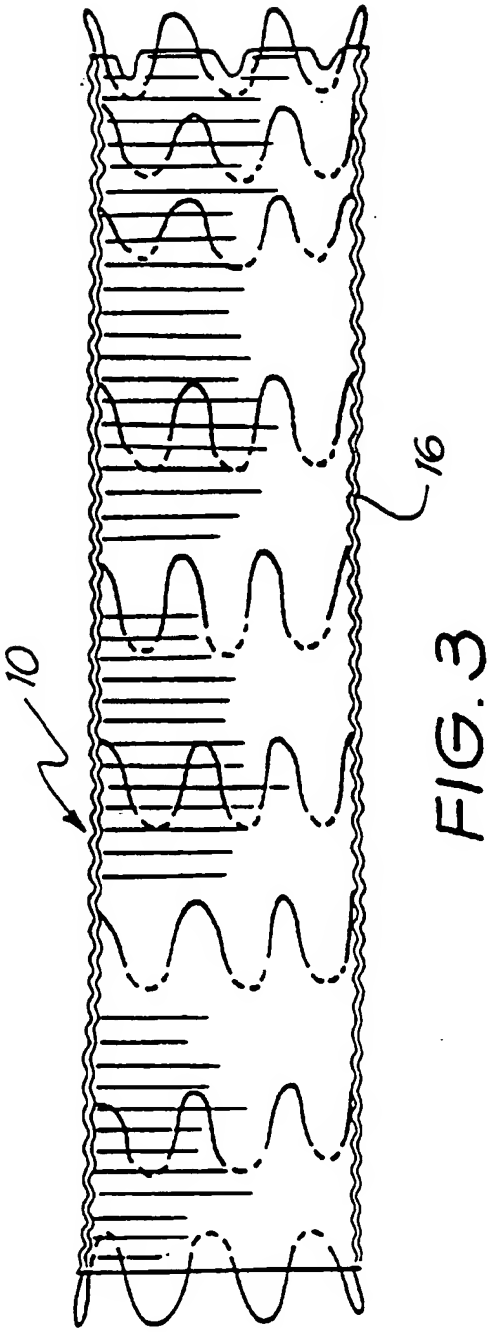


FIG. 3

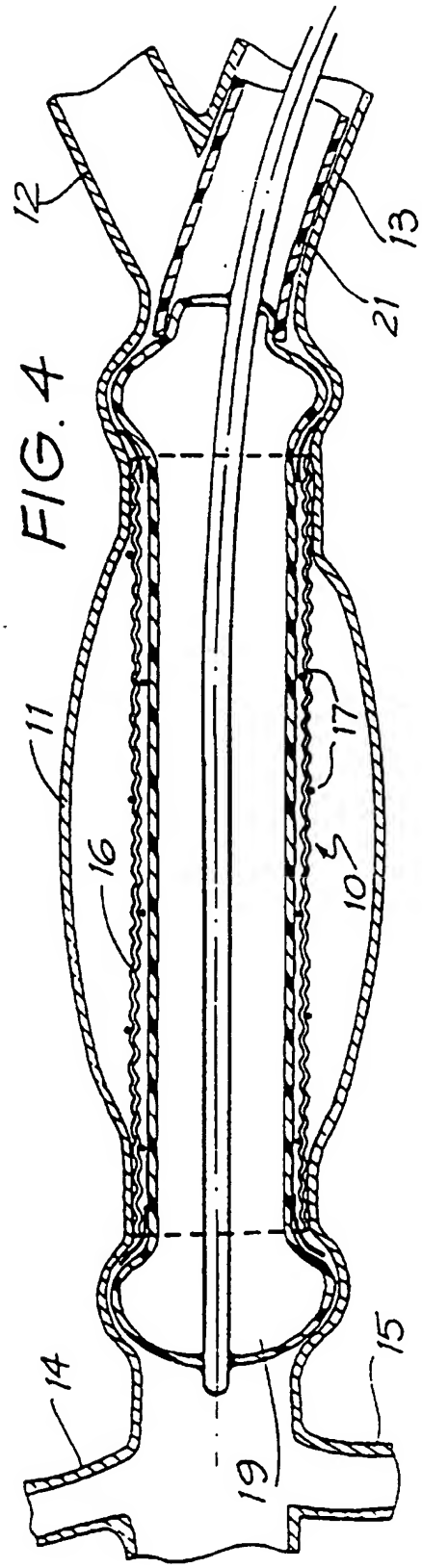


FIG. 4

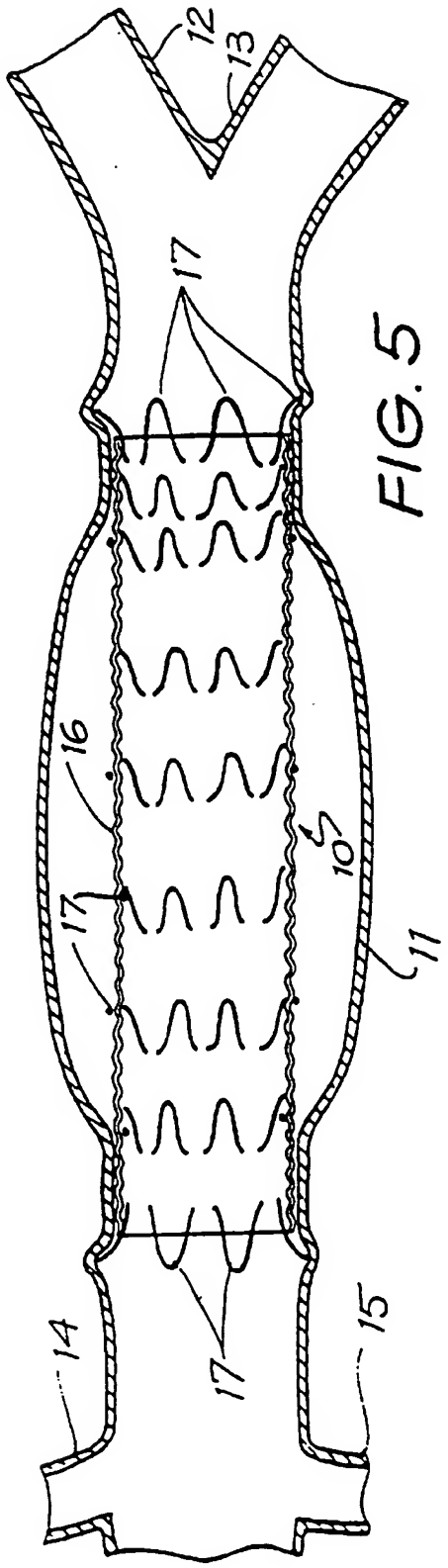


FIG. 5

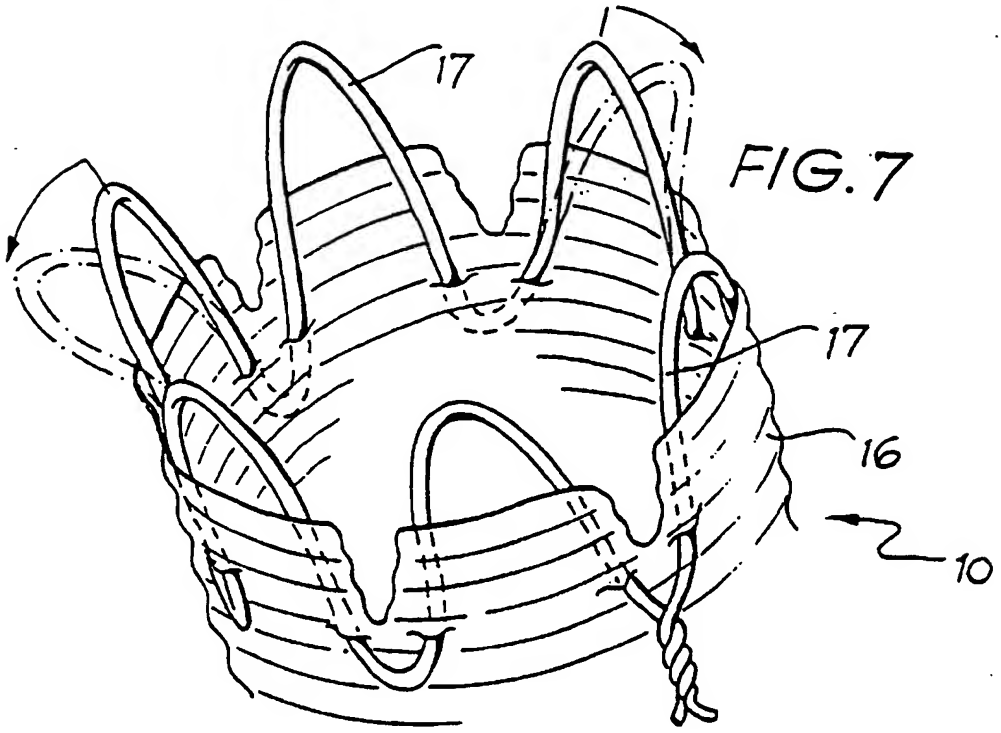
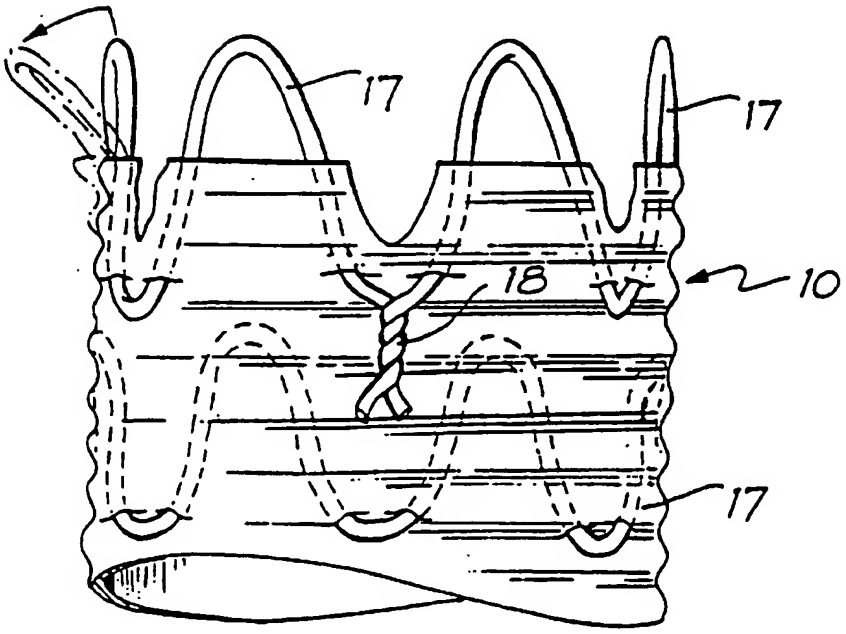


FIG. 7

FIG. 6



INTRALUMINAL GRAFT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 09/071,731, filed May 01, 1998, which is a continuation of application Ser. No. 08/446,672, filed Jul. 20, 1995, now U.S. Pat. No. 5,782,904, which is a Patent Cooperation Treaty national stage proceeding of application PCT/AU94/00586, filed Sep. 29, 1994.

This application claims priority to Australian application PM 1537, filed Sep. 30, 1993.

FIELD OF THE INVENTION

The present invention relates to an intraluminal graft for use in treatment of aneurysms or occlusive diseases.

BACKGROUND ART

It is known to use stents and intraluminal grafts of various designs for the treatment of aneurysms such as aortal aneurysms and for the treatment of occlusive diseases such as the occlusion of blood vessels or like ducts such as the bile duct and the ureter (which are all hereinafter called "vessels"). It is known to form such an intraluminal graft of a sleeve in which is disposed a plurality of self expanding wire stents (see Balko A. et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms", Journal of Surgical Research 40, 305–309 (1986); Mirich D. et al, "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" Radiology, Vol. 170, No. 3, part 2, 1033–1037 (1989)). Such intraluminal grafts are inserted through the femoral artery into the aorta in a catheter. Upon the release of the graft from the catheter it expands to the size of the aorta above and below the aneurysms and bridges the aneurysms.

There are a number of problems associated with such known grafts. These include the problem of twisting or kinking of the graft when it has to extend along a non-linear path which, twisting or kinking can lead to occlusion of the lumen of the graft; lack of precise control of the expansion of the graft in the lumen; avoidance of inadvertent separation of a supporting stent and the covering sleeve; and maintaining the graft against longitudinal movement along the lumen in which it is placed. The present invention is directed to an alternative form of intraluminal graft which provides an alternative to the known grafts.

DISCLOSURE OF THE INVENTION

In a first aspect the present invention consists in an intraluminal graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond at least part of that end.

In another aspect the invention relates to a method for positioning an intraluminal graft as defined above comprising introducing a catheter into a vein, artery or other vessel in the body, causing an intraluminal graft as defined above to be carried through the catheter on an inflatable balloon until the graft extends into the vessel from the proximal end of the catheter, inflating the balloon to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel, deflating the balloon and withdrawing the balloon and the catheter from the vessel.

In preferred embodiments of the invention each end of the graft will be provided with a wire which has alternate crests or apices extending beyond the adjacent end of the graft body. While the graft will normally have wires at each end of the graft with their crests extending beyond the graft body it may be necessary or desirable for a surgeon to shorten a graft and this may be achieved by cutting off part of the graft body. In this case the graft will have extending crests at only one end.

The projection of alternate crests or apices of the end wire or wires beyond at least part of the end or ends of the graft body is an important feature of this invention. As the graft is expanded by a balloon the expansion of the wires, and of the balloon, will be limited by the diameter of the tubular graft body except in the region of the alternate crests or apices of the end wire or wires. The balloon will be able to expand these crests slightly more than the remainder of the wire so that they bell outwardly away from the adjacent end of the graft body. The crests are forced into contact with the wall of the vessel and thereby become at least partly embedded into the vessel wall. This belling out of the crests of the wires at one or both ends of the graft body into contact with the inside surface of the vessel wall and then being at least partly embedded in the wall will assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion. The wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen. This allows the intraluminal graft to be used in situations in which the aneurysm to be bridged commences closely adjacent divergent blood vessels. In most cases there will be crests of wire actually projecting totally beyond the end of the graft materials. It would, however, be possible to have flaps of graft material protruding up the outside of each crest even though intermediate the crests the end of the graft stops well short of the crests. In this latter arrangement the crests are still free to bell outwardly as has been described above even though the crests do not extend absolutely beyond the end of the graft.

It is preferred that the one wire has a greater amplitude than at least the next adjacent one or two wires. This allows the wires at the end of the graft to be positioned more closely together than would be the case if they were all of the same amplitude. It is desirable to space the wires adjacent the end of the graft that will be placed "upstream" in the patient as close together as is possible as the neck of the aneurysm with which the graft is engaged can be quite short. Close spacing of the wires maximises the number of wires reinforcing that part of the graft in contact with the neck of the aneurysm. The spacing of the rest of the wires is desirably greater than those adjacent the one end of the graft as this avoids unnecessarily reducing the flexibility of the graft.

The wavelength of the wires in the graft is preferably substantially the same when compressed however when expanded the end wires will have a shorter wavelength than the intermediate wires as the intermediate wires will not bear against the arterial wall and may therefore be more fully expanded.

It is preferred that the edge of the one end of the graft is scooped out or scalloped between each projecting crest of the one wire. This reduces the possibility that a piece of the graft between those crests could project into the arterial lumen and partially occlude it or direct blood around the outside of the graft.

The tubular graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE. The tube

material is preferably crimped along its length to increase its flexibility, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention the graft body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall. The length and diameter of the graft body will be determined by the individual circumstances of the application to which the intraluminal graft is to be put. Typically, the vessel will be assessed by X-ray or other similar examination and a suitably dimensioned graft selected for that application.

The wires are preferably formed of stainless steel or another metal or a plastic which is maleable and is biocompatible. Each wire is preferably woven into the fabric of the graft body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the graft body during introduction of the graft or throughout its life. If the graft body is of a woven material the wires may be interwoven with the graft body during its production or alternatively they may be interwoven with the graft body after its manufacture. If the graft body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the graft body. The interweaving of the wires with the graft body has been found to be particularly desirable as it prevents separation of the wires from the graft body which could have serious adverse consequences. It has also been found that this technique is very good for causing the graft to expand effectively with the wires.

In alternative embodiments the wires may be held in place by sutures or adhesives or may be sandwiched between layers of a multi-layered tubular graft body. In all of the foregoing arrangements the wires are preferably disposed substantially within the graft body. It is, however, within the ambit of the invention that the wires may be connected to, and be disposed on, the outside surface of the graft body.

The intraluminal grafts according to this invention may be used to treat aneurysms or occlusive disease. In addition to treating aortic aneurysms they are particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery. The presence of the metal wires in the intraluminal grafts according to this invention assists in placing the graft as the wires are X-ray detectable. As the wires are arrayed along the length of the graft the complete position of the graft in the body can be continuously monitored.

The grafts according to this invention are typically substantially of constant diameter along their length ie, they are substantially cylindrical. It is possible, however, for the grafts to be frusto-conical in shape with a diameter that increases, or decreases, along the length of the graft.

The ends of the wires are joined together to form a tail which is preferably on the outside of the graft body and is positioned to lie along its radially outer surface. The ends may be joined by welding, by being twisted together or in any other suitable manner. The ends of the wires may inadvertently perforate the vessel in which the graft is placed, however, any such perforation will be occluded by the graft body thus ensuring that such a perforation will not adversely affect the patient. The ends of adjacent wires are preferably spaced apart radially about the graft body so as not to affect its flexibility and to avoid a line of ends engaging the wall of the vessel. The ends of adjacent wires preferably project in opposite directions along the vessel body. When the intraluminal graft is inserted into a vessel those wire ends which engage the inside surface of the vessel wall will assist in preventing the graft from inadvertent movement along the vessel. Causing the ends of alternate wires to project in opposite longitudinal directions along the graft body will assist in preventing longitudinal movement of the graft along the vessel in either direction.

In some circumstances it is desirable to insert two or more overlapped intraluminal grafts according to the present invention. In this case the first or upstream graft preferably has at its downstream end a "skirt" without reinforcing wires. This skirt is typically 10 to 15 mm in length. The second or downstream graft is inserted into the downstream end of the first graft and is expanded to engage with it. There is preferably an overlap of at least 10 mm however the degree of overlap is often adjusted so that the downstream end of the second graft is correctly placed in the downstream neck of the aneurysm being treated. This can lead to a greater overlap than is the minimum required but is a useful technique to ensure that the overall length of the graft is correct.

It is sometimes the case that the aneurysm extends up to or slightly beyond an arterial bifurcation. In such a case it is possible to place a graft according to the present invention which has a bifurcation at its downstream end, a so-called "trouser graft", wholly within the primary artery. A supplemental graft may then be introduced through each of the subsidiary arteries and overlapped with the respective lumenae of the bifurcated part of the primary graft. In the case of an aneurysm in the aorta, for instance, that extended into each of the iliac arteries the primary graft of the "trousers" type would be placed in the aorta through one of the iliac arteries. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the iliac arteries.

In those cases where one graft according to this invention is to be inserted into the downstream end of another such graft it may be desirable to provide means to stop the "skirt" on the downstream end of the other graft from being distorted by the insertion of the one graft. This may conveniently be done in one or other of two ways. The skirt may be provided with a small number of linear reinforcement wires extending longitudinally of the graft. In this case, the wires are spaced about the circumference of the skirt. Alternatively, the skirt may be provided with at least one resilient annular reinforcement wire. The resilient reinforcement wire will spring into an expanded condition upon being released from the catheter through which it is introduced into the body. This latter arrangement is particularly suitable in the case of "trouser grafts" wherein one leg of the graft will have a skirt which cannot be expanded by a balloon catheter.

BRIEF DESCRIPTION OF DRAWINGS

Hereinafter given by way of example is a preferred embodiment of the present invention described with reference to the accompanying drawings, in which:

FIG. 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by an intraluminal graft according to the present invention;

FIG. 2 is a side elevational view of the intraluminal graft of FIG. 1;

FIG. 3 is a longitudinal sectional view through the intraluminal graft of FIG. 2;

FIG. 4 is a detailed longitudinal sectional view through the intraluminal graft of FIG. 2 as it is being expanded into contact with the aorta of a patient during placement;

FIG. 5 is a detailed longitudinal sectional wire through the intraluminal graft of FIG. 2 after it has been inserted into the aorta of a patient;

FIG. 6 is a detailed elevational view of one end of the intraluminal graft of FIG. 2; and

FIG. 7 is a detailed perspective view of the one end of the intraluminal graft of FIG. 6 showing how the alternate crests of the end wire of the graft are pushed radially outwardly during insertion of the graft.

BEST MODE OF CARRYING OUT THE INVENTION

The intraluminal graft **10** is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of the aneurysm present in the aorta. As is seen in FIG. 1 the aorta **11** is connected to the left and right femoral arteries **12** and **13**. The aortic aneurysm is located between the renal arteries **14** and **15** and the junctions of the femoral arteries **12** and **13** with the aorta **11**. The graft **10** is, as will be described subsequently in more detail, inserted inside a catheter introduced into one of the femoral arteries **12** or **13** in a leg of the patient. Once the catheter is located appropriately with its proximal end in the aorta **11** the graft **10** is ejected from the catheter and expanded so that each end is in intimate contact around its full periphery with the aorta **11**. The graft **10** then bridges the aneurysm and isolates any thrombosis or gelatinuous material associated with the aneurysm outside the graft **110** to reduce the risk of embolisation.

The intraluminal graft **10** comprises a crimped tube **16** of woven Dacron. The tube is reinforced along its length by a number of separate and spaced apart stainless-steel wires **17** (each of which has a generally closed sinusoidal shape). The wires **17** are preferably as thin as possible and are typically 0.3 to 0.4 mm in diameter. The wires **17** are maleable and may be bent into any desired shape, ie they are not resilient to any substantial extent so that they have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience. The wires **17** are each woven into the fabric of the tube **16** such that alternate crests of each wire **17** are outside the tube **16** with the remainder of that wire **17** inside the tube (except in the case of the endmost wires as will be hereinafter described). The ends of each wire **17** are located outside the tube **16** and are twisted together to form a tail **18**. The tails **18** of alternate wires **17** are bent to extend in opposite longitudinal directions along the outside surface of the tube **16**.

The endmost ones of the wires **17** overhang the respective ends of the tube **17** so that alternate crests of those wires extend longitudinally beyond the end of the tube **16**. The endmost wire **17** preferably has an amplitude of about 6 mm and a wavelength such that between six and eight crests are spaced around the circumference of a 22 mm diameter graft. The next two adjacent wires **18** preferably are spaced as close as possible to the wire **17** and respectively have amplitudes of 4 mm and 5 mm. These wires will typically have the same wavelength initially as the wire **17**. Thereafter throughout the graft **10** the wires **18** are spaced at 15 mm intervals, have an amplitude of 6 mm, and have substantially the same initial wavelength as the wire **17**.

In use the graft **10** is radially compressed about an inflation balloon **19** (see FIG. 4) and the assembly is inserted into the end of a sheath catheter **21**. The sheath catheter **21** is inserted in a known manner through the femoral artery into the aorta **11** until the proximal end of the catheter **21** is beyond the proximal end of the aneurysm. The balloon **19** and the collapsed graft **10** disposed on it, are held stationary and the catheter withdrawn until the graft **10** is fully exposed and spans the aneurysm. The balloon is then inflated to expand the graft **10**. The diameter of the tube **16** determines the maximum expansions of the majority of the graft **10** and this diameter has been selected in advance by X-ray examination, or the like, to be substantially equal or only very slightly larger than, the diameter of the undistended aorta **11**. The balloon is, however, able to expand the alternating crests of the end wires **17** so that they are pushed firmly into contact with the wall of the aorta. These radially outwardly displaced crests serve to more effectively restrain the graft **10** against longitudinal movement relative to the aorta.

What is claimed is:

1. A prosthesis comprising:

a bifurcated base graft structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

a second graft structure which is adapted to be anchored within one of the flow lumens of said bifurcated base graft structure to form a continuous extension of that lumen;

wherein at least one of the bifurcated base graft structure and the second graft structure comprises a first end, a second end and a wire member having at least a portion adjacent to the first end, the wire member including a plurality of projecting apices, and wherein the first end includes an edge which is scalloped between projecting apices of the wire member.

2. The prosthesis of claim **1** wherein the second graft structure is adapted to be anchored within one of the divergent flow lumens.

3. The prosthesis of claim **1** wherein said wire member is sutured to the prosthesis.

4. The prosthesis of claim **1** wherein at least a portion of one of the bifurcated base graft structure and the second graft structure comprises PTFE.

5. The prosthesis of claim **1** wherein at least a portion of one of the bifurcated base graft structure and the second graft structure comprises a biocompatible material.

6. The prosthesis of claim **1** wherein the wire member is formed of a metal.

7. The prosthesis of claim **1** wherein the wire member is formed of stainless steel.

8. The prosthesis of claim **1** wherein the wire member is disposed at least in part on an outside surface of the prosthesis.

9. The prosthesis of claim **1** wherein the wire member is disposed substantially on an inside surface of the prosthesis.

10. The prosthesis of claim **1** wherein the wire member is interwoven with the surface of the prosthesis.

11. The prosthesis of claim **1** wherein the wire member is X-ray detectable.

12. The prosthesis of claim **1** wherein the second graft structure is frusto-conical in shape with a diameter that increases or decreases along the length of the second graft structure.

13. The prosthesis of claim **1** wherein the second graft structure is substantially cylindrical.

14. The prosthesis of claim **1** wherein a downstream end of the bifurcated base graft structure is provided with at least one resilient reinforcement wire.

15. A prosthesis comprising:

a bifurcated base graft structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

a second graft structure which is adapted to overlap and be attached to one of the flow lumens of said bifurcated base graft structure to form a continuous extension of that lumen;

wherein at least one of the bifurcated base graft structure and the second graft structure comprises a first end and a second end, and wherein at least one of the first and the second ends is reinforced with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end.

16. The prosthesis of claim **15** wherein the first and the second ends are each reinforced with a wire structure which has a plurality of apices extending beyond the first and the second ends.

17. A prosthesis comprising:

a bifurcated base graft structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

a second graft structure which is adapted to overlap and be attached to one of the flow lumens of said bifurcated base graft structure to form a continuous extension of that lumen;

wherein the second graft structure is adapted to overlap and be attached to one of the divergent flow lumens.

18. The prosthesis of claim **17** wherein one of the bifurcated base graft structure and the second graft structure is reinforced by a metal wire structure.

19. The prosthesis of claim **18** wherein at least a portion of said metal wire structure is X-ray detectable.

20. The prosthesis of claim **18** wherein the metal wire structure comprises a plurality of wireforms.

21. The prosthesis of claim **20** wherein each wireform of the plurality of wireforms has a closed sinusoidal shape.

22. The prosthesis of claim **17** wherein each of the bifurcated base graft structure and the second graft structure comprises an inlet end and at least one outlet end;

wherein the prosthesis is adapted to be placed in a lumen of a first vessel that intersects with a second vessel such that at least one of the inlet end of the bifurcated base graft structure and the outlet end of the second graft structure is placed adjacent said intersection between the first vessel and the second vessel; and

wherein the at least one of the inlet end of the bifurcated based graft structure and the outlet end of the second graft structure is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding inlet end of the bifurcated base graft structure and outlet end of the second graft structure and across a lumen of the second vessel without occluding it.

23. A prosthesis comprising:

a bifurcated base graft structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

a second graft structure which is adapted to overlap and be attached to one of the flow lumens of said bifurcated base structure to form a continuous extension of that lumen;

wherein at least one of the bifurcated base graft structure and the second graft structure comprises a first end and a second end, and wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the wire structure apices extend across a lumen of a first vessel that opens into a second vessel in which the prosthesis is being placed without occluding the lumen of said first vessel.

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